Queen Margaret University

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A REALIST EVALUATION OF THE CONTRIBUTION OF LEAN SIX SIGMA TO PERSON-CENTRED CULTURES IN A UNIVERSITY HOSPITAL

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Abstract

Background: Lean Six Sigma, a quality improvement methodology, has been used in healthcare since 2001. Person-centred approaches to healthcare improvement are now widely advocated in political, policy and practice discourse. Literature shows quality improvement practitioners are often unaware of or pay little attention to Lean Six Sigma's philosophical roots, seeing it less as an organisational philosophy but more as a quality improvement tool for continuous improvement. A lack of fidelity to Lean Six Sigma's philosophical roots can create a division between person-centred approaches to transforming care experiences and services, and quality improvement methods focusing solely on efficiency and clinical outcomes. There is little research into, and a poor understanding of, the mechanisms and processes through which Lean Six Sigma education influences healthcare staff's person-centred practice.

Aim: To address the question: *whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person-centred care and cultures.*

Design and methods: Realist review identified three potential Context, Mechanism, Outcome configurations (CMOcs) that explained how Lean Six Sigma influenced practice, relating to staff, patients and organisational influences. A realist evaluation explored how staff interacted with a Lean Six Sigma education programme (the intervention). Specifically, the CMOc relating to staff was adjudicated by study participants to determine whether, to what extent and in what ways it influenced person-centred care and cultures. Data collection was informed by person-centred principles and took place through a series of workshops and semi-structured interviews, followed by a review of research participants' improvement projects outcomes.

Findings: Three focused CMOcs, Aspects of Organisational Culture, the Organisation's Receptivity and Participants' Self-perception, emerged from the adjudication of the CMOc relating to staff, illuminating the contextual factors (C) that facilitated the outcomes (O) that arose from the underlying mechanisms (M) that were active when the contextual factors (C) were present. Synergies (respect for persons,

voice of the customer, staff empowerment and observational studies), an influencer (quality) and divergences (core values, standardisation and first principles) between participants' Lean Six Sigma practice and person-centred care and cultures were also revealed.

Discussion: A return to Lean Six Sigma's philosophical roots facilitates coherence in the philosophy, intention, methods and outcomes between Lean Six Sigma and person-centred approaches. Their combined use is not only possible but may also be desirable, enabling Lean Six Sigma practitioners to work in ways that support the development of quality, person-centred care that takes account of the outcomes for, and experiences of, patients, their families and staff. Incorporating person-centred principles into the research design, whilst adhering to the principles and rigour of realist evaluation, resulted in a new way of adjudicating CMOcs and novel methods of working with research participants. This study contributes to the evidence base on the study of quality improvement beyond the effectiveness of interventions alone. The findings will be of interest to researchers, policymakers and practitioners globally.

Keywords: Lean, Six Sigma, Lean Six Sigma, Process improvement, Person-centredness, Person-centred care, Person-centred cultures, Kaizen.

Dedication

I respectfully dedicate this thesis to the following beautiful people.

Elizabeth (Bettina) Teeling, August 2nd 1928 - August 3rd 2013. 'Always and Forever'.

Lydia Emerson Smith, February 23rd 1995 - January 26th 2019. 'A ray of sunshine'.

Gráinne Ahern, May 12th 1977 - January 10th, 2020. 'It's all Good'.

James (Jem) Teeling, September 15th 1929 – 29th May 2002. 'Safely home'.

To my wonderful husband, Martin - 'All that we have promised, all that has come before, all that is yet to come and all that we now share'.

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Chapter 1: Focus, Biography and Structure of the Thesis

1.1 Introduction

This thesis is concerned with the effects of the quality improvement methodologies of Lean, Six Sigma and Lean Six Sigma on healthcare practices, and their potential influence on person-centred care and cultures. The study's participants are healthcare professionals from a range of disciplines who are qualified Lean Six Sigma practitioners. Empirically, the study is a realist evaluation of participants' experiences of using Lean Six Sigma in their practice, with a specific focus on this question: for whom, in what circumstances and how Lean Six Sigma contributes to person-centred care and cultures. Theoretically, the thesis elicits and presents participants' collective adjudication of the programme theory that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of a university education and training programme.

As the study investigates person-centredness, person-centred values and principles influenced the design and conduct of the realist evaluation. Hence, person-centred principles and realist evaluation methodology informed the design and implementation of the methods. This chapter introduces the quality improvement methodologies of Lean, Six Sigma and person-centredness, outlines the background to the study, discusses my personal PhD journey and concludes with a description of the thesis structure.

1.2 Lean Six Sigma and Person-centred Care and Cultures

Lean Six Sigma has been used in healthcare since 2001 in the United Kingdom (UK) and since 2002 in the United States of America (USA) with Lean, Six Sigma and Lean Six Sigma now considered to be some of the most popular process improvement methodologies in healthcare internationally (Radnor & Osborne, 2013, Williams, 2015; Jorma et al., 2016). Similarly, since the millennium political and policy stakeholders have widely advocated that person-centred care should be at the heart of the health system (Bartz, 2010; Toro, 2015; World Healthcare Organisation [WHO],

2016; International Council of Nursing [ICN], 2017; Nolte 2017). Lean Six Sigma combines both Lean and Six Sigma methodologies to minimise identified non-value-adding healthcare process activity and unwanted process variation. Lean Six Sigma health outcomes have been broadly categorised as affecting processes of care, quality of care, finances, and patient and staff satisfaction (Deblois & Lepanto, 2016). Customer requirements and staff engagement are important factors in the application of Lean and Six Sigma (Radnor et al., 2012; Williams, 2015, 2017; Aboelmaged et al., 2015; Abu Bakar et al., 2015; Teeling, Dewing & Baldie, 2020).

Person-centredness refers to embedded practices within a specific type of culture that enables and facilitates the delivery of person-centred care (Hardiman & Dewing, 2019). Person-centred cultures are necessary for the delivery of person-centred care (McCormack and McCance, 2017). Person-centred care has an explicit focus on ensuring the client or patient is at the centre of care delivery (McCormack et al., 2015) and is concerned with every person involved in the patient's care, not just the patient (McCormack & McCance, 2006; 2010; 2017).

Internationally, whilst there is a body of research on Lean Six Sigma, there is little research on its specific influence on person-centredness. Given the popularity of Lean Six Sigma with its potential for cost savings and increased efficiency in healthcare, and a continuing need for the development of person-centred cultures, it is important to explore the relationship between Lean Six Sigma and person-centred methodologies, any synergies or divergences that exist, and their implications for practice internationally.

1.3 Rationale for Study

Dixon Woods (2019) suggests that the study of quality improvement methodologies in healthcare contributes to, and is important in developing an evidence-base that looks at more than improvement interventions alone. There is a lack of theoretical and empirical research on the influence of Lean Six Sigma on person-centred care and person-centred cultures, and the relationship between them. This is the first study to address an important gap in the empirical and theoretical literature.

1.4 Research Aim

The first principle of Lean is the concept of 'Kaizen' (good change) that originates in the three main features of the Japanese management philosophy, which are: harmony and loyalty, consensus in decision-making and employment for life (Suárez-Barraza et al., 2011). Additionally there is an understanding of value as a broader principle (Williams, 2015) taking as its starting point peoples' experiences, values and beliefs (Teeling, Dewing & Baldie, 2020). However there has been a continuing drift from the principles of Lean (Marksberry et al., 2011; Simon & Houle, 2017), resulting in Lean Six Sigma practitioners often being unaware of, or paying little attention to its philosophical roots (Imai, 1986; Wittenberg, 1994; Gondhalekar et al., 1995; Wackerbarth et. al., 2021), seeing Lean less as an organisational philosophy (Lawal et al., 2014; Flynn et al., 2018) but more as a quality improvement tool for continuous improvement (Radnor et al., 2012; Burgess & Radnor, 2013; Wackerbath et al., 2021). This can lead to a disconnect between innovative person-centred approaches to transforming the experience of care and service delivery, on the one hand, and Lean Six Sigma use as an improvement method that ignores its philosophical roots and focuses solely on efficiency and clinical outcomes. Internationally healthcare systems are required to use finite resources with greater efficiency. Combined with a continued focus on patients' clinical outcomes, this tends to favour Lean Six Sigma as an improvement methodology. At the same time, however, there is an increasing emphasis on improving the staff and patient experience (Nicosia et al., 2018; Moraros et al., 2016). This favours person-centred approaches.

The aim of this study is to address the question: whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person-centred care and cultures. The objective is to understand how staff who have undertaken a university Lean Six Sigma education and training programme understand and experience, in their specific contexts of practice, the contribution of Lean Six Sigma to person-centred care and cultures. This will contribute to knowledge of how Lean Six Sigma and person-centredness can be used together in future process improvements through highlighting the synergies and divergences between both methodologies.

1.5 The Lean Six Sigma Education and Training Programme

Between 2014 and 2020, a Lean Six Sigma education and training programme, a joint undertaking between University College Dublin (UCD) and the Mater Misericordiae University Hospital (McNamara & Teeling, 2019) has delivered one hundred and fifty process and quality improvement projects in over fifty healthcare institutions and Community Healthcare Organisations (CHOs) in Ireland. Lean Six Sigma projects were undertaken to improve service delivery from the perspectives of both patients and staff. The University based education and training programmes in Lean Six Sigma for Healthcare include an introduction to Lean Six Sigma (White Belt), a Professional Certificate in Lean Six Sigma (Green Belt) and a Graduate Diploma in Lean Six Sigma (Black Belt) which can be taken as stand-alone qualifications or as part of an MSc in Leadership, Innovation and Management in Healthcare. Over two thousand health service employees across Ireland have undertaken a UCD education and training programme on the use of Lean Six Sigma for process and quality improvement and healthcare institutions nationally have adopted Lean Six Sigma as a methodology for improvement. Relevant to this study is my position as both the researcher and as a lecturer on the Lean Six Sigma education and training programme (the intervention). It is important to note this position as an insider conducting research, acknowledging my insider status and considering the potential implications. Failure to declare or recognise insider status is according to Herr & Anderson (2005, p.47) 'deceptive and allows the researcher to avoid the kind of intense self-reflection that is the hallmark of good insider research'. This position as an insider researcher is discussed in chapters four and eight.

1.6 Study Site

The site in which this research took place, the Mater Misericordiae University Hospital (known as the Mater), is a university hospital, founded as a charitable voluntary hospital in 1861 by Catherine McAuley and the Sisters of Mercy. It has been one of Ireland's foremost centres for medical, nursing and allied health professional training and has been a teaching partner to UCD since its foundation. In an Irish context, the

population is classified into one of seven social class groups which are ranked on the basis of occupation, with social class one being professional worker and social class five being semi-skilled workers. The hospital has a catchment area that includes both the highest number of socio-economic class five patients and the highest number of patients aged over sixty-five nationally. It is a busy working environment with 600 beds and 3000 core staff. Specialties include the National Heart and Lung Transplant Unit, the National Spinal Injuries Unit and the National Isolation Unit. Like other healthcare institutions, and particularly as the location of the National Isolation Unit, the hospital has been particularly busy during the SARS-CoV-2 (Covid-19) pandemic of 2020.

1.7 Study Design

The study design is based on realist evaluation methodology (Pawson & Tilley, 1997, 2001; Pawson, 2000, 2002, 2006, 2013; Tilley, 2004, 2008). Realist evaluation is a theory-based evaluation designed to test and refine a theory that has informed the development of multiple and varied programmes or interventions. Pawson (2002) sees realist evaluation as a form of theory-based evaluation specifically developed to strengthen the explanatory power of evaluation studies. Theory-based evaluations are, according to Hansen (2005), unlike many result and process evaluation models, as they focus not only on outcome measurements but also on the mechanisms and contexts that support, or hinder, the realisation of those outcomes. Similarly, Lean Six Sigma used as an improvement evaluation model attends to linear before and after trends and patterns that influence improvement. Pawson (2013) reiterates the importance of the realist evaluator understanding that realist valuation focuses less on whether an intervention worked but rather on how it did or didn't work and why. The initial programme theory of this research is that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD education and training programme (section 1.5).

Consequently, this study:

- Ascertains what it is about Lean Six Sigma that works for participants in what circumstances.

- Captures all contextual factors.
- Recognises that it is people who make programmes work.
- Takes account of the complexity of social programmes.

(Pawson, 2013)

The aim of Realist Evaluation is to understand 'what works, for whom, in what circumstances and why' (Pawson & Tilley, 2007). This means rather than solely providing judgements on a programme's success or failure, there is an appreciation that the underlying causative factors must also be investigated and understood.

1.8 My PhD Journey

I have had many and varied roles throughout my thirty-two-year nursing career. I completed my general nursing studies in London in the 1980s and my children's nursing studies in Dublin in the 1990s and have worked in both major teaching hospitals and smaller community units. At an early stage in my career I developed an interest in operating department nursing, working in anaesthetics, surgery and post-acute care as a staff nurse, a clinical nurse manager, practice development manager and eventually as the operating department manager at the Mater hospital, a major adult acute teaching hospital. In 2004, I was seconded from the hospital for eight years to a Department of Health and Health Service Executive campus development team where I worked as a clinical planner on the building of a new 65,000m^2 campus for the Mater. During this time, I developed an interest in quality and process improvement and particularly in Lean and Six Sigma methodologies, collectively Lean Six Sigma. Both approaches to improvement were developed in industry.

As I trained in both methodologies, I became proficient in their use and began to apply them in my practice. Subsequently, when I completed my secondment and returned to the Mater hospital in 2013, I worked with the Chief Executive Officer (CEO) and Director of Quality and established, and became the founding manager of, a new Lean Academy, the first of its kind in Ireland, and affiliated with the Mater hospital's academic partner, UCD. As the Academy facilitated process improvement initiatives that achieved significant improvements in patient outcomes, I discerned over time that

something was missing. I perceived that although the intervention of Lean Six Sigma was showing impressive results in quality and improvement projects and patient outcomes, a more 'human' factor was missing.

In 2014, having spoken on the use of Lean Six Sigma in healthcare at a conference in Galway, I heard Professor Jan Dewing's keynote address on the concepts of person-centredness, person-centred care and person-centred cultures. McCormack and McCance (2006, 2010, 2017) suggest that person-centred care is about every person involved in the patient's care, not just the patient. Person-centredness is, according to Dewing and McCormack (2016), in ascendancy as a particular type of approach and culture that applies to everyone in the organisation, staff, patients and families alike. Although I had heard of these approaches to improvement before, I had never really paid attention to their implications both for myself as an individual and for my practice. However, as I listened, I realised that I had found the missing 'human factor' in my Lean Six Sigma work. It was for me the 'Eureka!' moment. I spoke to Professor Dewing and suggested undertaking a PhD on the relationship between Lean Six Sigma and person-centredness and she agreed that the topic had research potential. An initial review of the literature indicated to me that there was little or no research on the combined use of Lean Six Sigma and person-centredness in healthcare practice settings. Bringing this initial finding to the CEO of the Mater hospital, an advocate of both Lean Six Sigma and person-centredness, I secured her support to undertake a PhD in the area. I contacted Professor Dewing who agreed to be my supervisor. This was the genesis of this study to explore the relationship between Lean Six Sigma and person-centred methodologies, any synergies or divergences, and their implications for practice. Thus began my six-year PhD journey with Queen Margaret University (QMU), joining the Student International Community of Practice (SICoP), travelling to Edinburgh for doctoral studies and SICoP events, and becoming part of a group of diverse, international and inspirational PhD students.

I have since carried my research forward to my current role, a joint appointment combining a lectureship in process and quality improvement in UCD and work on continuous process improvement projects in practice areas within the Mater. During my PhD studies I undertook a year-long practice development programme with QMU

and the Irish Health Service Executive (HSE) to facilitate my own understanding of person-centredness and person-centred care, and to become a facilitator of person-centred cultures. Today, I work with hospitals and Community Healthcare Organisations nationally, and I see my role as an advocate of the integration of Lean Six Sigma and person-centred methodologies as more important than ever. Central to the overall research and this thesis is my ongoing aim to understand how the use of both methodologies together might facilitate improvements not only in patient outcomes but also on patients' and employees' experiences of care. I am delighted to now be in a position to share this research with others, so that healthcare staff working with both Lean Six Sigma and person-centred approaches to improvement may find it useful in their own practice.

1.9 Structure of Thesis

This thesis follows a paradigmatic structure to outline the research rationale, process and findings.

- Chapter one has introduced the researcher, and provided a rationale for and overview of, the research.
- Chapter two comprises a realist review of literature to identify initial Context Mechanism Outcome configurations (CMOc) relevant to the programme theory. First, the chapter elaborates on Lean Six Sigma, its introduction, implementation and use in healthcare, the context of, and outcomes from, its successful use, and its strengths and weaknesses as a process improvement methodology. Next, there is discussion on person-centredness, person-centred care and person-centred cultures. Finally, comparison is made between the key theoretical and methodological principles underpinning each approach to improvement, enabling identification of the synergies, and divergences between Lean Six Sigma practice and person-centred care and cultures.
- Chapter three outlines the philosophical approach to the research. It discusses my axiology, ontology and epistemological commitments, as well as those of critical realism. It then examines the strengths and weaknesses of approach and, finally, illustrate why Realist Evaluation is a suitable methodology to answer the research questions.

- Chapter four presents the methods used for data collection, coding and analysis, together with the rationale for each method, and the rigour applied in undertaking the study.
- Chapters five, six and seven present the study's findings, to enable insight and understanding of the research participants' experience of the intervention, the Lean Six Sigma programme, and of the identified CMOc 'Lean Six Sigma and Staff' within which it operates. The chapter summarises participants' collective experiences, and their adjudication and refinement of the CMOc.
- Chapter eight discusses and contextualises the findings through all stages of adjudication of the CMOc and the extent to which the research aim, objectives and questions were addressed. It explores the findings and considers their implications for theory, research, policy and practice as well as the challenges of implementing them, the study's limitations and delimitations, and directions for future research.

1.10 Summary

This chapter has summarised my journey to and through this study and my reasons for undertaking it. It has given a high-level overview of Lean Six Sigma and person-centredness, the methodologies central to this study. The study's rationale, aim and design were also outlined. Finally, it set out the structure of the thesis. The thesis now continues with chapter two, a realist review of the literature.

Chapter 2: Realist Review

2.1 Introduction

A realist review is a specific type of literature review comprising a theory-driven and interpretive review of the literature. It is explicitly concerned with explaining the outcomes of complex intervention programmes and with understanding and explaining the interaction between context, mechanisms, and outcomes of intervention programs (Pawson, 2006; Pawson et al 2004; Pawson et al., 2005; Wong et al., 2012; Berg & Nanavati, 2016). The purpose of this realist review is to establish whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person-centred care and person-centred cultures. The questions guiding this review are designed to determine, according to the published literature, the influence of Lean Six Sigma on person-centred care and person-centred cultures. Using a Realist Evaluation methodology, initial Context Mechanism Outcome configurations (CMOcs) are developed to guide the study. The CMOc model derives from a critical realist epistemological approach based on the work of Pawson and Tilley (1997) and seeks to develop answers to underlying research questions; i.e., what are the underlying causative mechanisms (M = mechanism) that operate in the 'real' world (C = context) that help to capture the extent to which an intervention works (O = outcome).

This chapter illustrates how Lean Six Sigma is associated with and contributes to both person-centred care and person-centred cultures, and the conditions in which this is achieved. The questions that have guided the realist review are:

1. What is the impact of Lean Six Sigma on the quality and improvement of healthcare delivery?
2. How is Lean Six Sigma represented and portrayed in the literature in relation to the concepts of person-centred care and person-centred cultures?
3. Whether and to what extent are the principles of person-centred care and person-centred cultures evident in Lean Six Sigma thinking and practice?
4. Does Lean Six Sigma have an impact on the formation of person-centred cultures and the practice of person-centred care?

The chapter begins by discussing Lean Six Sigma in relation to its component parts, Lean and Six Sigma. The concepts of Value Add and Non-value Add are explored. Next, the application of Lean Six Sigma in a healthcare setting is contextualised by looking at the implications of its use for outcomes for patients, their families and staff. This then leads into a discussion on the impact of Lean Six Sigma on the organisation and its culture.

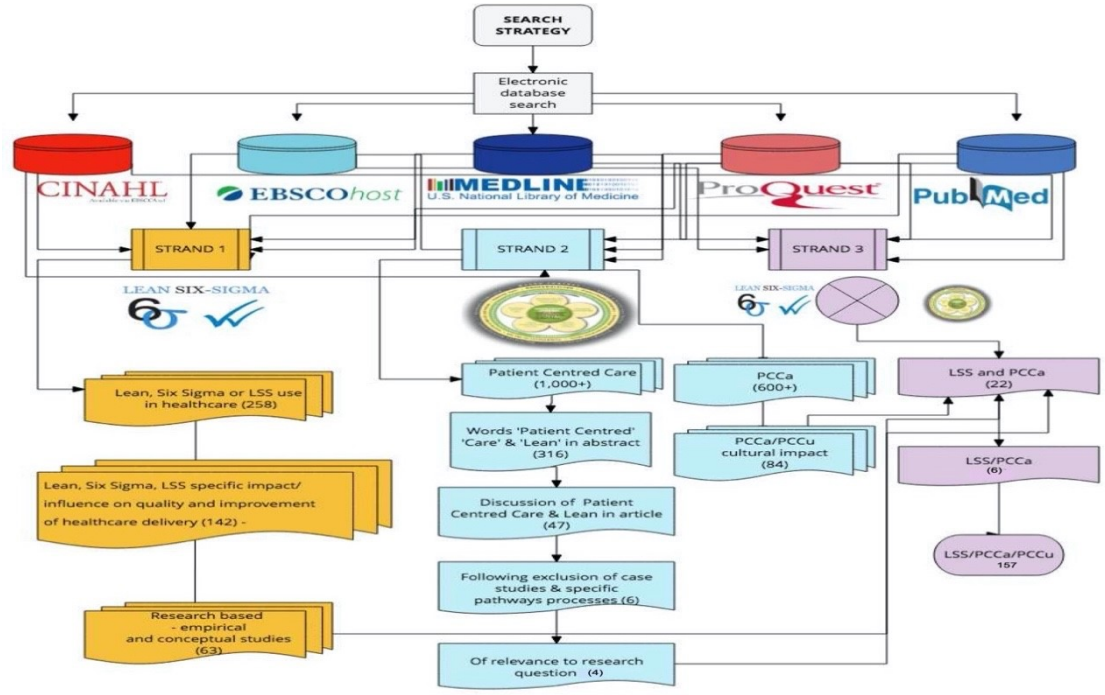
Following this, there is a review of the concepts of person-centred care and person-centred cultures, the concept of personhood and the development of person-centred care. This is followed by a discussion of the literature on Lean Six Sigma and person-centred care and cultures, and the extent to which Lean Six Sigma is associated with person-centred care. This enables identification of areas of synergy and divergence between Lean Six Sigma, person-centred care and person-centred cultures. Following this, there is an assessment of Lean Six Sigma implementation in the context of person-centred care and person-centred cultures and a review of methodological weaknesses within the Lean Six Sigma framework. Finally, initial CMOcs are developed which were then adjudicated using empirical data from the subsequent realist evaluation (see chapter four).

2.2 Method

The realist review, which was carried out in 2016-2017, involved a three-strand search approach (figure 2.1) to identify literature that could answer the four review questions in relation to each of the following:

1. Lean Six Sigma and its application in healthcare.
2. The practice of person-centred care and how person-centred cultures are developed.
3. The contribution of Lean Six Sigma to person-centred care and person-centred cultures.

Figure 2.1 Literature Search Strategy overview



The databases CINAHL, EBSCOhost, Proquest, Medline and PubMed were initially used to identify studies that were relevant to the review questions and involved Lean Six Sigma, person-centred care and person-centred cultures or a combined use of both Lean Six Sigma and person-centred care methodologies in healthcare. The studies encompassed both empirical and conceptual work. Opinion or editorial pieces were excluded. Across all three strands, reference lists of retrieved articles were examined for the key search terms in their titles and affiliated searching of the reference lists of retrieved items was also conducted to identify further research articles not identified through the keyword searches. The following inclusion and exclusion criteria were applied in order to narrow the search results:

1. Work published relating to Lean Six Sigma in healthcare in the English language between 2000 and 2017; the rationale for this being that Lean Six

Sigma was first introduced into healthcare settings early in the decade.

2. Work relating to strand one (Lean Six Sigma) that discusses the concept of patient-centred care but also references person-centred care or person-centred cultures.

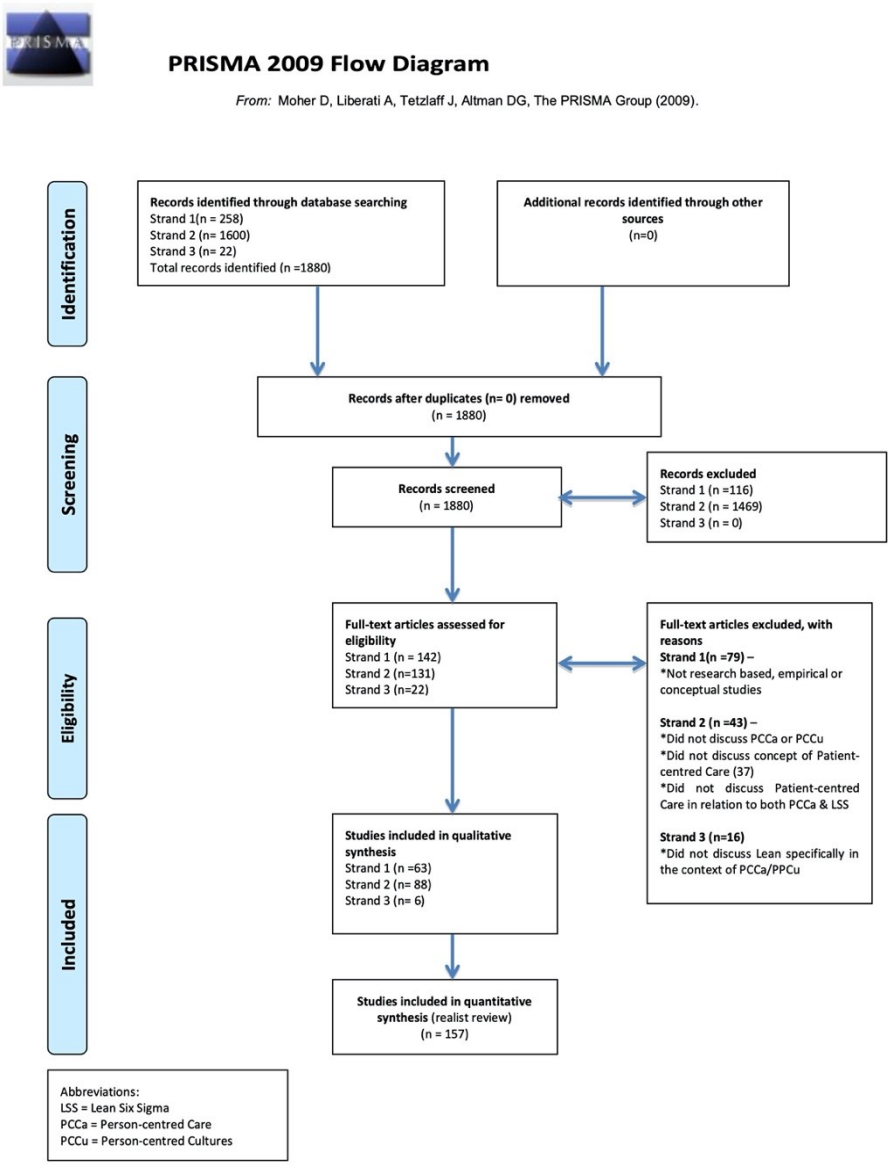
3. Work relating to person-centred care and person-centred cultures from 1995 to 2017; the rationale being that this was a period of 'strong academic momentum and practice emergence' (Edvardsson, 2015).

4. Work meeting criteria 1-3 that was peer-reviewed and available as full-text journal articles with a complete bibliography.

Papers were excluded that did not meet these four inclusion criteria as well as discursive opinion or editorial pieces.

These criteria facilitated a comprehensive and high-quality yield of papers for review (figure 2.2), carried out over a thirteen-month period from August 2016 to September 2017. Relevant literature from 2017-2020 was reviewed in an update to this chapter in January 2020.

Figure 2.2 Prisma Flow Diagram



Source: Taken from template by Liberati et al. (2009, p 4)

2.2.1 Strand 1

Key search terms used in combination for the first strand were: ‘Lean’, ‘Six Sigma’, ‘Lean Six Sigma’, ‘process improvement’ ‘quality improvement’ and ‘healthcare’. The search indicated that there was little published on Lean in healthcare before 2000, with the majority of output commencing in 2004 and increasing steadily to 2017. The ‘gap’ in the years 2000-2004 may be accountable to Lean application in healthcare

commencing in the early noughties, with little evidence base to support publications at this early stage. The literature search in strand one yielded 258 articles which describe or mention the use of Lean Six Sigma in healthcare. Detailed analysis of the abstracts and application of the inclusion and exclusion criteria reduced this initially to 106 articles, further refined on reading of full papers to 63. These focused on direct patient care with the quality of the patient experience and clinical outcomes the key focus. They also examined specific areas of application such as the whole organisation, a department or a specific service. All of the literature includes reference to the origins of Lean in the Toyota management system before detailing its application in healthcare. Sixty percent of the articles (n=38) were classified as empirical, using case studies or surveys, with 40% (n=25) being theoretical articles informed by reviews of the literature to discuss the development of Lean Six Sigma theory in healthcare.

Articles which analysed empirical data using methods such as Randomised Control Trials (RCT) were included as they were likely to provide the highest level of evidence for an intervention-based research question. The majority of clinical case studies applicable to Lean Six Sigma were implemented in the United States of America reflecting the early start of Lean healthcare there after 2000 (Womack et al., 2005; Spagnol et al., 2013). In an update to this chapter in 2020, nine additional clinical case studies using Lean Six Sigma within Irish healthcare settings were noted for inclusion, six of which had taken place at the study site (Creed et al., 2018; Brown et al., 2019; Davies et al., 2019; McGrath et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019; Connolly, Teeling & McNamara, 2020; Donegan et al., 2021).

2.2.2 Strand 2

The second strand search utilised the key words ‘person-centred’, ‘person-centredness’, ‘person-centred cultures’, ‘patient-centred’ and ‘patient-centredness.’ This served two functions:

1. To clarify the difference between patient-centred and person-centred approaches, identifying literature which had a patient-centred as opposed to person-centred care approach for exclusion.

2. To develop an understanding of person-centred care and person-centred

cultures to enable subsequent review in the context of Lean Six Sigma.

To clarify the difference between patient and person-centred care, the initial search strategy yielded a large body of literature (over 1000 articles) discussing the concept of patient-centred care. Of these, 316 had the words 'Lean', 'Patient' and 'Centred' in the abstract. However, on further review, only 47 articles discussed Lean and patient-centred care. Upon reading these articles in full, those that discussed the concepts of patient-centredness (n=6) were identified. From these, four articles (including one publication from 2019 as part of the chapter update) mentioned Lean and patient-centred care and also referred to a person-centred approach. These were therefore deemed relevant for inclusion.

The search identified over 600 articles specific to person-centred care or person-centred cultures, with 180 peer-reviewed and eight books by one author alone, all important in developing an understanding of the concepts of person-centred cultures and the practice of person-centred care. The literature on person-centred care and person-centred cultures clearly highlights the difference between the concepts of patient-centredness and person-centredness; the focus of this review is on the latter.

Person-centredness is, according to Dewing and McCormack (2016), in the ascendancy as a particular type of culture that takes account of everyone in the organisation, staff and patients alike. The person-centred care, person-centred cultures literature was reviewed in relation to this cultural impact, with a focus on 84 publications between 1995 and 2017 that referred to the understanding, development and measurement of person-centred cultures.

2.2.3 Strand 3

The third strand of the search utilised a combination of the keywords from strands one and two to fully address the research questions. Despite the steady increase in the volume of literature on Lean Six Sigma deployment in healthcare, very few studies have been published on Lean or Six Sigma and their contribution to person-centred care and person-centred cultures. In total 22 publications were found which refer to person-centred care when discussing Lean use in healthcare; however, only six publications specifically discuss Lean in the context of person-centred care (Veech,

2004; Kelly, 2013; Williams, 2015, 2017; Colldén et al.,2017; Dunsford and Reimer, 2017), with one of these (Kelly, 2013) cited repeatedly. There were no incidences of literature referring to Six Sigma and person-centred care. However, given Six Sigma's emphasis on customer voice, stakeholder engagement and quality, there was potential that the literature reviewed could reveal synergies between Lean Six Sigma and person-centred care and cultures. The initial review of the available literature therefore indicated that few researchers working in healthcare have undertaken research into the contribution of Lean, Six Sigma or Lean Six Sigma to person-centred care or person-centred cultures, and that the topic has not been studied in any depth.

2.2.4 Reflection on Review

The decision to include patient-centred care in Strand 2 generated a large amount of work in reading articles (n=47) and yielded four articles relevant to the study. However, this was a necessary strategy as it avoided the risk of omitting any important links between Lean Six Sigma and person-centred care.

2.2.5 Literature Review Structure

This literature review, congruent with the research design and methodology (chapters three and four), applies realist philosophy to the synthesis of findings from primary studies that have a bearing on the research questions: a realist review (Wong et al., 2013). For the purposes of clarity on the concepts of Lean Six Sigma in healthcare and the contribution of Lean Six Sigma to person-centred care and person-centred cultures, the literature review is structured under the following headings:

2.3 Lean Six Sigma
- 2.3.1 Introduction
- 2.3.2 Lean
- 2.3.3 Six Sigma
- 2.3.4 Lean Six Sigma
- 2.3.5 Summary

2.4 Lean Six Sigma in Healthcare

2.4.1 Introduction

2.4.2 The evolution of Lean and Six Sigma use in healthcare

2.4.3 Lean Six Sigma and the patient

2.4.4 Lean Six Sigma and staff

2.4.5 Lean Six Sigma and organisational culture

2.4.6 Summary

2.5 Person-centred care and cultures

2.5.1 Introduction

2.5.2 Defining person-centred care in healthcare

2.5.3 Person-centred care in healthcare

2.5.4 Person-centred care and Lean Six Sigma

2.5.5 Lean Six Sigma, person-centred care and person-centred cultures: synergy and divergence

2.5.6 Revisiting the philosophical roots of Lean Six Sigma and Person-centred care and cultures

2.5.7 Summary

2.6 CMOcs developed from the realist review

2.6.1 Introduction

2.6.2 CMOcs from the realist review

2.6.3 Summary

2.7 Conclusion

2.7.1 Introduction

2.7.2 Reflection and next steps

There now follows the findings of the review.

2.3 Lean Six Sigma

2.3.1 Introduction

Williams (2015) claims that many and varied quality improvement initiatives have been applied in healthcare to improve processes and system management, including Lean, Six Sigma and Lean Six Sigma. According to Jorma et al. (2016) there are many approaches for process management, which include Lean, Six Sigma, Lean Six Sigma and Total Quality Management (TQM). The authors also suggest that there are many definitions of Lean. This section discusses the literature on Lean, Six Sigma, and the combination of both as Lean Six Sigma and how they have been developed and applied in healthcare.

2.3.2 Lean

Shah and Ward (2007) suggest that despite a myriad of academic papers and case studies, there is still no one confirmed definition of Lean. However, Scherrer-Rathie et al. (2009) state that Lean is a multi-faceted concept and is well defined in the literature. The term 'Lean' has been used to describe the philosophy of the Toyota Production System (TPS) (Womack and Jones, 2003; Kollberg et al., 2007; Aherne and Whelton, 2010; Leite and Vieira, 2015) developed in the car manufacturing industry. Syrett and Lammiman (1997) claim that Lean can be seen as a 'coherent philosophy' that introduces new ways of working or doing things that can be considered 'leanness'. Moore (2001) asserts that Lean should be viewed more as a philosophy rather than a process. Olexa (2002a, b) and Bateman (2002) recognise that Lean can be seen as a set of tools or a methodology but claim that, in order to support the concept and sustain any Lean improvements, Lean must be viewed as a philosophy. Bhasin and Burcher (2004) suggest that Lean initiatives fail when Lean is viewed as a set of tactics and not embraced as a philosophy. This view of Lean as a philosophy and not just a toolset for change is widely supported in the literature with Lean seen as a 'way of thinking' across an organisation (Schonberger, 1996; Bartezzagni, 1999), a 'mindset' (Elliot, 2001), a 'way of doing business' or a 'business philosophy' (Liker, 2004) with a cultural impact (Henderson et al., 1999) that requires people to believe in it (Vasilash, 2000). Liker (2004) suggests that it is this view of Lean as a philosophical approach in tandem with a focus on people and process that enables an organisation to

become ‘Lean’. Graban (2012) sees Lean as a management system, a methodology and a philosophy that can support employees and enable them to deliver better care to their patients. Williams (2015, 2017) contends that the view of Lean as a philosophy is important as otherwise its application in healthcare organisations will not benefit from any of the lessons learned from its application in industry.

With its origins in the motor industry, Lean is often seen as a cost reduction measure; however, it is concerned with improving processes and healthcare organisations comprise a series of processes designed to deliver value to those who use, work or depend on them (Institute for Healthcare Improvement [IHI], 2005). Graban (2016) dismisses the oft-heard disclaimer from healthcare workers who, when asked to engage with Lean, say ‘but people are not cars’, arguing that his ongoing work in the use of Lean in healthcare has found it to be a flexible methodology, embracing culture, and a management system that focuses on developing people to solve problems. Graban (2016) further emphasises that Lean is not about ‘building cars’. dos Reis Leite and Vieira (2015) suggest that health services, as with any service, have issues with quality that are a real challenge for managers and staff, and which lend to Lean for improvement. Bowen and Youngdahl (1998), sometimes named the ‘fathers of Lean service’, were the first to conduct studies on the transfer of Lean from the manufacturing industry to the service industry. Their seminal 1998 work looked at the application of Lean in a healthcare setting, specifically a hospital, and showed benefits in healthcare process improvement. Zidel (2006) and Aherne and Whelton (2010) describe ‘Lean’ as a quality improvement approach that consists of the elimination of waste (steps that do not add value in the eyes of the customer) to improve the flow of people, information or goods. In healthcare there can be both internal customers (e.g., a doctor orders a blood test and becomes a customer of the pathology service), and external customers, (e.g., patients, their family and friends).

The majority of the reviewed literature on Lean in healthcare makes reference to the Toyota Production System (TPS) and its adoption, use and development in healthcare settings (Waldhausen et al., 2010; Belter et al., 2012; Ford et al., 2012; McDermott et al.,2013). Healthcare organisations that have adopted Lean give form to the idea of

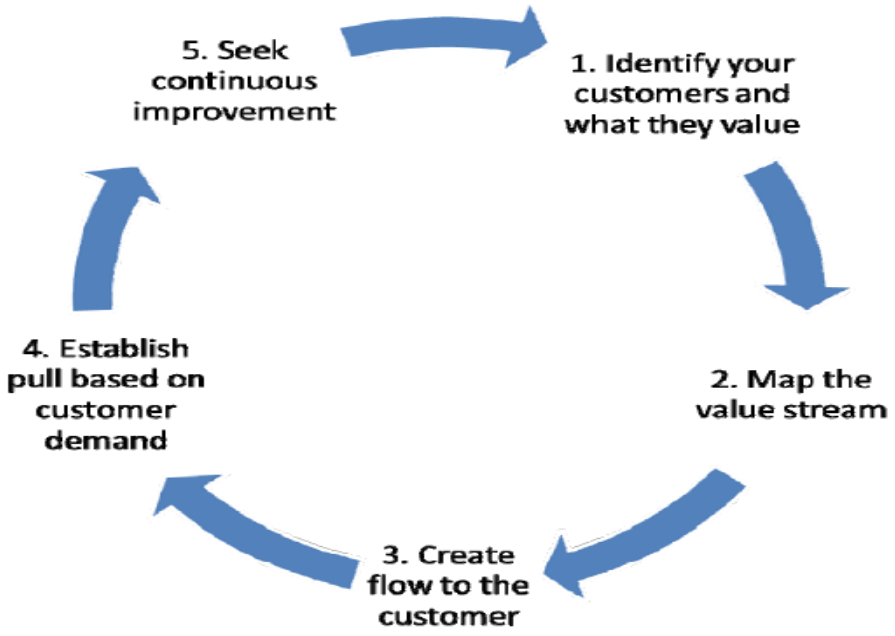
constantly striving for continual improvement (IHI, 2005; Graban and Toussaint, 2011). Whilst Lean was developed for car manufacturing and utilised in engineering and production operations, other industries quickly picked up on the inherent benefits and it is now used in pharmaceutical, electronic and healthcare settings, with noted improvements to process flow, impacting on factors such as patient wait times, releasing time to care, error reduction and improved patient outcomes (Aherne and Whelton, 2010; Dodds, 2011; Jay, 2011; Teixeira Lot et al., 2018). Based on a case study charting seven years' experience of Lean healthcare programmes and Lean thinking at Thedacare in the USA, Toussaint and Gerard (2010) credit Lean with doubling productivity and reducing costs through implementation of sustainable operational improvements in patient outcomes and staff morale. Antony et al. (2019) discuss how Lean has been adopted for healthcare process improvement even in fundamentally different healthcare contexts such as the predominantly private system in the USA and the National Health Service (NHS) in the UK, which provides care that is free at the point of entry.

Despite a perceived dearth of Lean literature on the service sector (Piercy and Rich, 2008), this literature review has revealed a large volume of case studies on Lean implementation in healthcare globally (Miller, 2005; Aherne and Whelton, 2010; Graban, 2012). Results from a survey by the American Society for Quality (ASQ), published in 2009, indicated that 53% of hospitals that responded had implemented Lean (ASQ, 2009). This widespread adoption has led to an increase in the number of scholarly studies of Lean application in Healthcare, with a steady annual increase in published papers (de Souza, 2009; Mazzocato et al., 2010; Antony et al., 2019; McNamara & Teeling, 2019; Teeling, Dewing & Baldie., 2020).

According to Womack and Jones (2003), the application of 'Lean' in healthcare is about shortening the time between the patient entering and leaving a care facility by eliminating Non-Value Add time and activity for patients and staff. This emphasis on eliminating patient waiting times is evident as part of Lean implementation (Hydes et al., 2012; Mazzocato et al., 2010, 2012) through the application of five principles (figure 2.3.) (Womack and Jones, 2003; Proudlove et al., 2008; Joosten et al., 2009).

The five principles for applying Lean start with an important first step: identifying who the customers are (patients and staff initially in healthcare). This leads to identifying what they want so that delivery of what they consider 'Value Add' can be planned. The principles of Lean promote making what the customer has identified as value and what they really want 'flow' to them, when they want it. The concept of 'perfection' is a theoretical endpoint, which occurs when the customer only receives value (Womack and Jones, 2003). This recognition of value is highly relevant in working with interdisciplinary teams of healthcare staff as many professions, including nursing, midwifery and medicine. Many authors (Nematollahi & Isaac, 2012; Doughty et al., 2007; Brown, 2012) talk about the value in bridging the gap that they experience between what they learn in the University and how they apply it in practice.

Figure 2.3 The Principles of Lean



Source: Taken from the Lean Enterprise Institute website (2015)

The principles of Lean are operationalised by the following eight steps (Marksberry et al., 2011; Simon & Houle, 2017):

1. Clarify the problem
2. Break down the problem
3. Set the target
4. Analyse the root cause

5. Develop countermeasures
6. Implement countermeasures
7. Monitor results
8. Standardise.

A comprehensive and systematic review of Lean over four decades by Stone (2012) discusses the evolution of Lean from an early ambiguous ideological state to its current perceived status as a transformational conceptual model. Stone's (2012) work is consistent with the incremental development of Lean from its genesis with Toyota in 1918, to its first documentation in 1965 (Teich & Faddoul, 2013), to its introduction to healthcare in the noughties (Jones, 2015) with early adopters and leaders including Virginia Mason Medical Centre and Thedacare in the United States (Barnas, 2011).

Although Stone's (2012) review is not specific to healthcare his identification of three perceived Lean knowledge voids is particularly useful for this study, these are:

1. The lack of links between Lean implementation and theory, with the majority of articles reviewed focusing on how to, or not to, implement Lean and lacking critique.
1. Little reference to the body of knowledge available on planned organisational change within the Lean literature. Kaizen is the Japanese concept of continual improvement, which can be in personal, home, social and working life (Imai, 1986), and is seen by some as a philosophy of life (Imai, 1986; Wittenberg, 1994; Gondhalekar et al., 1995). Burke (2008) (cited in Stone, 2012, p. 121) notes that the concept of Kaizen is a potential connection between theory and the 'Lean thinking paradigm' that is missing in much of the Lean literature. Stone (2012) concurs with Burke's (2008) assertion that this is an area that needs further exploration in Lean research.
2. The lack of research, evident in the literature reviewed, that looked at the development of staff within Lean organisations, with articles referring to this 'human factor' predominantly taking the form of critique. This is a crucial gap and feeds into this study's research question concerning Lean's contribution to

person-centred care and person-centred cultures. Lean and Six Sigma's impact on staff is discussed in section 2.4.

The literature on Lean in health care revealed a number of key issues for the overall research:

1. **Kaizen:** Kaizen has its origins in the three main features of the Japanese management philosophy: harmony and loyalty, consensus in decision-making and employment for life. These three features are all included in the Japanese concept of respect for people (Suárez Barraza et al., 2011) that has synergies with person-centred care theory which emphasises the development of person-centred cultures through collaborative, inclusive and participatory approaches (Dewing & McCormack, 2017). This is discussed in more detail later in this chapter. Guimarães and de Carvalho (2012) claim that when American firms began to utilise Japanese management styles, the focus was on only the continuous improvement aspect, with the cultural aspect of Kaizen not actually understood. Suárez Barraza et al. (2011) suggest that this focus on continuous improvement and not on Kaizen as a management philosophy, underpinned by principles and values, is detrimental to Lean engagement. Liker (2004) discusses the importance for Toyota of adapting its culture to local conditions. This is of particular interest given that Kaizen is relevant to engaging and supporting staff in any process improvement (Elgar and Smith, 1994) and this study examined Lean's impact on staff and wider organisational culture.
2. **Outcomes:** In relation to the outcomes of Lean application in healthcare, it is evident that Lean can deliver on what Jones and Woodhead (2015) terms quality, safe care, improving the healthcare experience for patients, and improving the work experience for staff.
3. **Contexts, Mechanisms and Outcomes:** As with Mazzocato (2012), this review has found that primary studies rarely describe contexts, provide explanations of the modes of action by which Lean works and the outcome the studies seek to understand. Critical realism and realist evaluation offers a useful methodology that will help develop a better and more nuanced understanding

of how Lean Six Sigma does or does not contribute to person-centred cultures and person-centred care.

4. **Need for Six Sigma:** George (2003) suggests Lean doesn't provide the organisational and analytical analysis, control and deployment mechanisms offered by Six Sigma. This perceived gap between Lean and Six-Sigma is discussed in section 2.3.4.

2.3.3 Six Sigma

Six Sigma is a data-driven process improvement methodology designed to improve process capability and enhance process throughput through the introduction of improvement projects (Pande et al., 2002; Rath and Strong, 2002; George, 2005). It is a quality improvement methodology and management system, focusing on data and costs (Bisgaard and Freiesleben, 2004). Six Sigma originated as a measurement standard of the normal curve by mathematician and astronomer Carl F. Gauss (1777-1855) and can be further traced as a measurement standard in product variation to the 1920s when Walter Shewhart, an American physicist, engineer and statistician, illustrated that the point in a process that requires correction is three sigma from the mean (Tennant Gower, 2001). Statistically, Six Sigma is now recognised as a metric for process improvement, denoted by the Greek Alphabet letter σ, a normal data distribution that seeks to achieve a quality level of 3.4 defects per million opportunities (DPMO) (Aboelmaged, 2011).

Former Motorola employee, Dr Mikel Harry, is credited with the development of what we now know as Six Sigma; however, the term 'Six Sigma' was coined by Motorola employee, Bill Smith, when, in 1987, he introduced it as a company-wide quality improvement methodology (Proudlove et al., 2008) to improve the reliability of Motorola products by reducing variation that caused defects in the manufacturing process (Antony, 2012). Six Sigma employs existing quality science tools, such as quality circles, developed by respected quality leaders which include Ishikawa, Deming, Juran and Drucker to name but a few (Fursule et al., 2012). Hoerl and Snee (2002) suggested three principles of statistical thinking that can illustrate how Six Sigma process improvement is applicable in a service setting (Antony, 2006):

1. Work takes place via a system of interconnected processes.
2. These processes are subject to variability.
3. Processes yield data that can explain Non-Value Add variability.

Antony (2006) suggests examples of where Six Sigma is useful in healthcare. They include areas such as reducing time to be admitted in the Emergency Department, reducing errors in diagnoses and reduction in surgical errors. In relation to error reduction, Greenberg et al. (2007) found that communication breakdowns are a common feature in surgical errors, with little data to guide improved communication. They suggest that in sixty surgical cases with 81 breakdowns in communication, a streamlined communication pathway with less variation would have led to a 73% initial improvement in error rates. This is an example of where Six Sigma would be used to reduce variation in a process.

According to Langabeer et al. (2009) and Antony (2006), there are four principles that distinguish Six Sigma from other quality improvement methodologies:

1. A focus on customer expectations of the service.
2. Continuous measurement of the errors or defects within this service.
3. Setting of tight goals to reduce these errors.
4. Measurements to track performance and a formal change implementation strategy.

Langabeer et al. (2009) suggest that delivering and monitoring quality person-centred care should be a priority goal for a healthcare organisation. Snee (1999, 2010) and Antony (2012) concur that Six Sigma is customer focused with the emphasis being on finding out what is Critical to Quality (CTQ) for customers in order to enable delivery on their expectations. Laureani et al. (2013) suggest that the Six Sigma principles are well suited to the healthcare environment where patients are our customers, as they advocate a 'zero tolerance' for mistakes and errors. The appropriateness of the terminology of 'zero tolerance' has been questioned in healthcare with healthcare organisations such as the Mason Institute (Plsek, 2013) using different terminology, such as zero defects. Cory et al. (2018) suggest that creating a clear terminology that

translates manufacturing-centric improvement language into healthcare-centric language is an important consideration when using process improvement methodologies such as Six Sigma in healthcare.

Six Sigma has a statistical and data-driven approach to problem solving (Antony, 2004, 2007, 2008). The Six Sigma approach is heavily data driven and this is why some staff find it difficult (poor data analysis skills) and time-consuming (time spent collecting and analysing data) with many staff expressing a preference for Lean which does not have the reliance on what George (2003) calls the 'analytical analysis of data'. The challenge of educating staff in Six Sigma as well as Lean methodologies cannot therefore be underestimated, and has led to the development of education programmes for staff in both Lean and Six Sigma with the qualification of what are termed Lean Six Sigma Green or Black Belts (Antony, 2012; McNamara & Teeling, 2019). The origins of the Lean Six Sigma 'Belts' terminology lies with Dr Mikel Harry who, whilst on sabbatical from Motorola in 1986-1987, spent three months working as a technical consultant at the Unisys Salt Lake Printed Circuit Facility. Having completed a Project using Six Sigma process improvement methodology, he was asked to train other staff. After brainstorming, the name 'Black Belt' was chosen because it sounded 'sexy', and thus the system of Belts began. The terminology may be popular, in use worldwide and a recognised American Society of Quality qualification, but it is not without its detractors. To the average layperson the term Black Belt is synonymous with defence and attack, so some companies changed the terminology e.g. Six Sigma Expert, Six Sigma Master Expert (Asefeso, 2014).

Organisations often rely on professionals with Six Sigma or Lean Six Sigma certifications to help maintain the rigour of the methodology, especially when it comes to statistics. However, with a limited number of these Lean Six Sigma experts, the organisation can ultimately experience resource constraints and find it hard to apply improvement to health care (Spagnol, 2013; Lin, 2016).

Six Sigma's data-driven approach provides the statistical evidence for change; however, there is a potential for what is has been called 'analysis paralysis' (Harry, 2013), where a large amount of time and human resources are spent collecting and analysing data instead of focusing on more rapid process improvements that can use

Lean. Six Sigma in its pure form can be perceived as a rigid programme that may or may not fit into an organisation's mission and values (Lin, 2016).

Six Sigma and Lean have demonstrable differences in their approach, and they can be used independently of each other to deliver outputs (table 2.1). A major difference that influences an organisation's choice of Lean or Six Sigma is speed (Viaya Sunder, 2013). Lean delivers faster results utilising graphics-based tools whereas Six Sigma is statistics heavy and more incremental in nature (Viaya Sunder, 2013; Lin, 2016). Many organisations often start with short-term Lean process improvement projects, which provide fast results, gather organisational support and can reveal deeper more complex process problems. When these more complex problems remain, a move to Six Sigma with its robust tools and methods can address them (De Koning et al., 2006).

Table 2.1 Differences between Lean and Six Sigma

Action	Lean	Six Sigma
End-to-end Value stream mapping	✓	X
Statistical analysis of Root Causes	X	✓
Visual Workplace (e.g. productive ward)	✓	X
Eliminate waste – improve flow	✓	X
Focus on variation reduction	X	✓
Control over monitoring improvement	X	✓
Rapid Improvement (30-60-90 days)	✓	X
Breakthrough improvement (incremental)	X	✓

Source: Adapted from Vijaya Sunder (2013, p.26)

Byrne et al. (2007) believe integration between Lean and Six Sigma as an improvement methodology brings many benefits to the organisation including maximising the quality of day-to-day processes.

2.3.4 Lean Six Sigma

A hybrid of Lean and Six Sigma as Lean Six Sigma appears in the healthcare literature from 2010 onwards (Abu Bakar et al., 2015) following Lean and Six Sigma integration for project delivery from early 2002 and increased use by 2008. The majority of this literature refers to the genesis of Lean and Six Sigma in Toyota and Motorola, respectively (Lawal et al., 2014). The experience of both the Virginia Mason Medical Centre and Thedacare in Lean, and of the Mount Carmel Health System in Columbus, Ohio, the Charleston Area Medical Centre in West Virginia and Thibodaux Regional Medical Centre in Louisiana in Six Sigma application are early examples of the successful introduction of these improvement methodologies into healthcare (Sehwail & DeYong, 2003; Van den Heuvel et al., 2005; Barnas, 2011; Kaplan et al., 2014). A combination of Lean, to eliminate Non-Value Add, and Six Sigma, to eliminate variation that contributes to Non-Value Add, constitutes Lean Six Sigma. Henrique and Filho (2018) in a review of the empirical literature on Lean Six Sigma found that it is one of the most frequent continuous improvement methodologies used for process and quality improvement in hospitals. What differentiates Lean Six Sigma from other quality improvement approaches is that it does not sit in one department (e.g. quality) but is disseminated across the organisation (Snee 2010). In addition, Lean focuses on the entire organisational value chain, while Six Sigma concentrates on certain projects or processes in an organisation.

Lean Six Sigma merges both Lean and Six Sigma process improvement methodologies (Black, 2009, Laureani et al., 2013) and works well in traditional process-driven settings such as production by removing Non-Value Add activity, reducing variation, standardising procedures and subsequently reducing costs (Liker, 2004; Eckes, 2007). Six Sigma gives structure to process improvement through a series of defined steps (Antony, 2006):

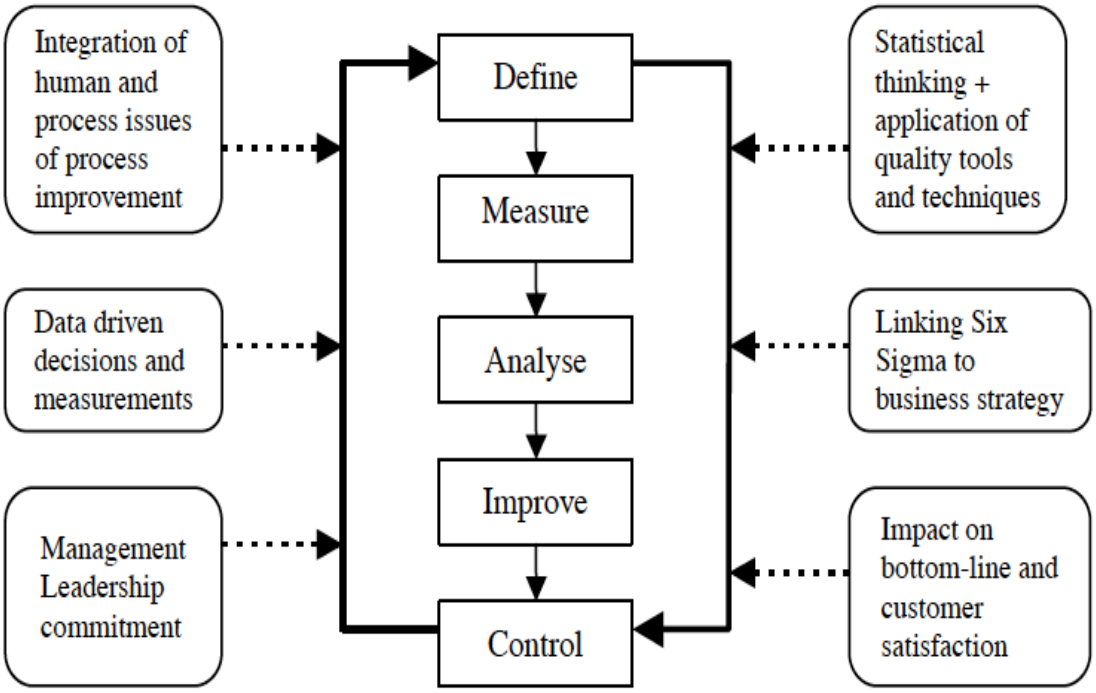
1. **D**efine the problem.
2. **M**easure the problem – gather data which illustrate the problem.
3. **A**nalysis of the problem data to discover root causes.
4. **I**mprovement of the problem through data driven solutions.

5. **C**ontrol to prevent reoccurrence through monitoring of the data.

The steps of Define, Measure, Analyse, Improve and Control (DMAIC) furnish a model for a structured approach (figure 2.4), initialised in a project overview document known as a Charter (Tjahjono et al*.,* 2010) with the model allowing for evaluation and re-evaluation of the project outcomes. Evaluation and re-evaluation is inherent in the Control Phase which mirrors the Model for Improvement Plan Do Check Act (PDCA) Deming wheel or Shewhart's cycle, a quality improvement methodology that allows for both single loop learning, where people, organisations or groups modify their actions according to the difference between expected and reached outcomes; and double-loop learning, where they modify their actions but additionally correct or change the underlying causes behind identified problems (Pietrzak & Paliszkiewicz, 2015).

In the DMAIC model, stakeholder or 'customer' engagement is sought from the outset at the Define stage. This stage aims to create value for the customer by identifying problems or issues that need solutions early on (Aapaoja et al., 2013), utilising the extensive knowledge base of customers and other stakeholders (Howell & Mitropoulus, 2002). Engagement with health service staff and patients is discussed in sections 2.4.3 and 2.4.4.

Figure 2.4 Six Sigma Methodology



Source: Taken from Antony (2006, p.239)

Synergies (table 2.2) exist between Lean and Six Sigma as they each take a process view and converge in their focus on variation, flow and the customer (Laureani et al., 2013) with the prime focus of Six Sigma being elimination of variation, and Lean focusing on removing waste in processes.

Table 2.2 Synergies between Lean and Six Sigma

Commonality	Lean	Six Sigma
Customer Focus	✓	✓
Management commitment required	✓	✓
Employee engagement paramount	✓	✓
Seeks to improve process	✓	✓
Cross-functional teams	✓	✓
Productivity/Cost saving benefit	✓	✓
Dedicated/Structured approach	✓	✓

Source: Adapted from Vijaya Sunder (2013, p.26)

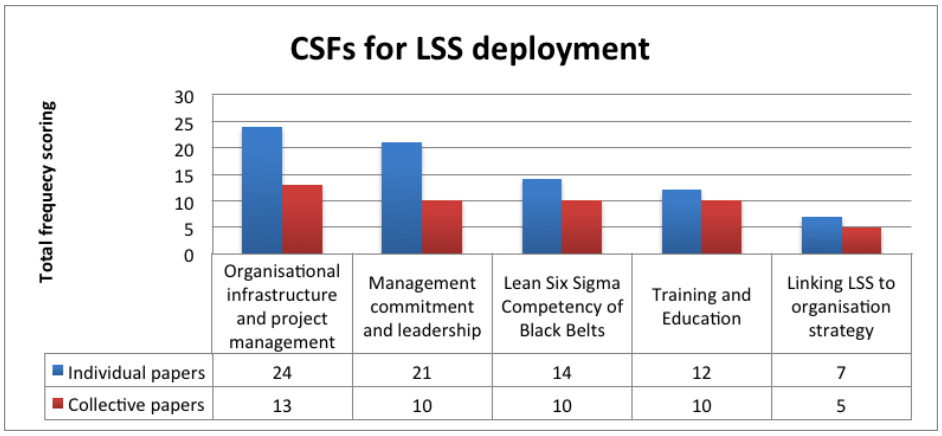
Both methodologies have a strong focus on the customer, the employee, management support and teamwork (Vijaya Sunder, 2013). One of key strengths of Lean Six Sigma is that it seeks to find the 'root cause' of problems in a process, which means that it utilises real-time observational data collection (Tolga Taner et al., 2007; Graban, 2012), the process of which is referred to as 'Gemba' in Lean terminology (Womack, 2013). The original Japanese terminology derives from *gembutsu*, which translates into English as 'real thing'. Gemba is effectively a real-time observational study of a person in the place where the work or activity occurs, mirroring the Japanese concept of Kaizen (change for the better) (Elgar & Smith, 1994). This form of non-judgemental observational study is not unique to Lean, with workplace observations being utilised in Practice Development (Dewing, McCormack & Titchen, 2014) to measure and evaluate 'where we are now'.

Langabeer et al. (2009) see Lean as promoting a 'doing the right thing' approach (value add) while Six Sigma focuses on 'doing things right' (no errors). The application of Lean Six Sigma allows the synergies (table 2.2) from each methodology to work in tandem to improve organisational processes (Snee 2010; Corbett, 2011) and has been found to be more effective than the use of either Lean or Six Sigma alone (Gremyr and Fouquet, 2012). De Koning et al. (2006) support the synthesis of the complementary strengths of Lean (customer-focus, quick-wins, waste-reduction) and Six Sigma (statistical tools, structured approach, pursuit towards perfection). In regard to 'doing the right thing' using Lean Six Sigma in healthcare delivery, this could include directly tackling variations (the Six Sigma component) in the quality of care and giving patients more 'information and choice' and quick access to this information (the Lean component) as recommended for example, in the Darzi report (2008), which was commissioned to examine quality measures including safety, effectiveness, timeliness, efficiency and equitability of care in the NHS and social care services in the UK.

Abu Bakar et al. (2015) undertook a review of existing literature on Lean Six Sigma as opposed to Lean and Six Sigma separately. Reviewing each of the selected papers (n=13), they identified five Critical Success Factors (figure 2.5) arrived at through counting the total number of times they were mentioned in the thirteen papers. The top

two Critical Success Factors were organisational structure and management support. The next two were the competency of the Black Belt facilitator and the standard of education, with Black Belt interpersonal skills also recognised as a key success factor (Hilton & Sohal, 2012). A limitation of this review is the small number of papers reviewed (n=13); however, each paper was specific to Lean Six Sigma as a hybrid of Lean and Six Sigma and was published between 2010-2013, making it relevant for this study. These Critical Success Factors can be seen as contexts in relation to developing initial CMOcs and is returned to in further analysis of Lean Six Sigma and organisational culture.

Figure 2.5 Critical Success/Contextual factors for Lean Six Sigma Deployment

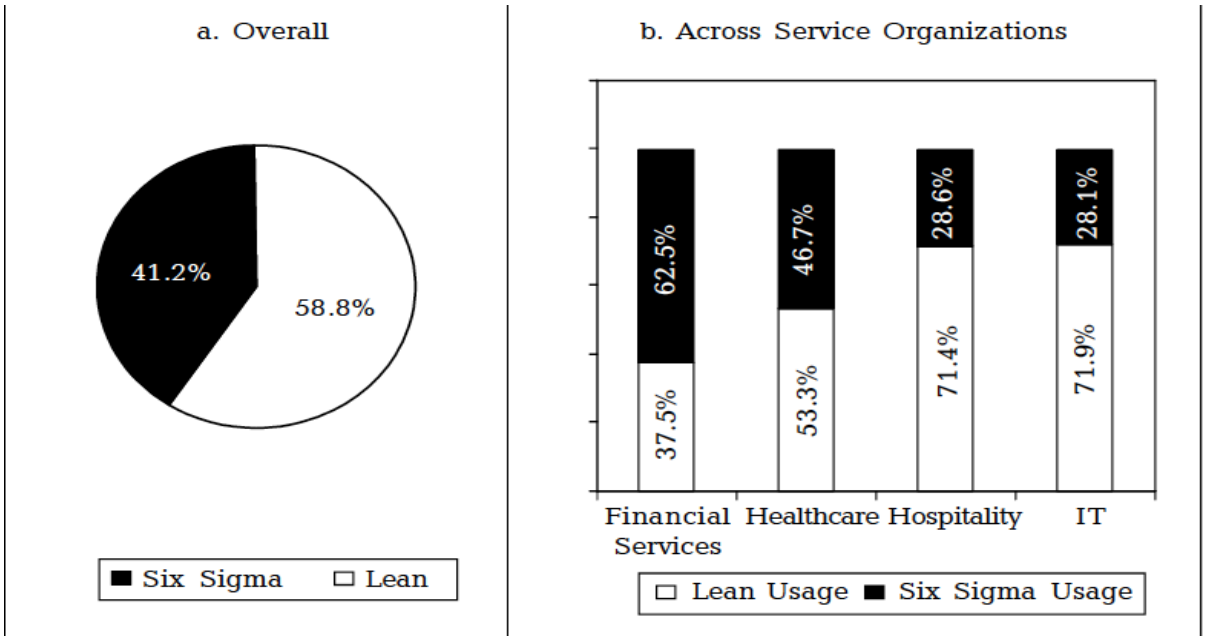


Source: Adapted from Abu Bakar et al. (2015)

Vijaya Sunder (2013) conducted a study to ascertain the views of Lean Six Sigma professionals (e.g. Black Belts) on Lean Six Sigma, its applicability and its usage. The study illustrated that 58.8% of the group favoured the use of Lean as opposed to 41.2% who preferred Six Sigma for process improvement (figure 2.6). As discussed earlier, Lean is often the first methodology used for faster solutions and organisational buy in, and Vijaya Sunder's (2013) finding that healthcare professionals prefer Lean rather than Six Sigma could be because, as Drucker (1993) suggested, healthcare organisations are the most complex form of human organisation we have ever attempted to manage. This complexity derives from a myriad of factors, including managing the sometimes incompatible interests and perspectives of physicians, nurses,

other healthcare professions and patients (Drucker, 1993). These issues are discussed further in sections 2.4.3 and 2.4.4.

Figure 2.6 Lean versus Six Sigma usage



Source: Taken from Vijaya Sunder (2013, p.25)

2.3.5 Summary

Lean and Six Sigma have been discussed as separate methodologies for use in process improvement with their differences and synergies highlighted. It has been illustrated how Lean Six Sigma combines both methodologies to minimise Non-Value Add and process variation. The key synergies of working to improve processes based on customer requirements and staff engagement are important factors in the application of the DMAIC model. The literature has revealed the findings of Lean Six Sigma professionals and researchers (table 2.3) which have highlighted potential Critical Success Factors in organisational structure and project management, management commitment and leadership, the Lean Six Sigma competency of Black Belts, education and training and linking Lean Six Sigma to organisational strategy. These have been useful in generating initial CMOcs for assessing Lean Six Sigma deployment in a healthcare setting in the context of its contribution to person-centred cultures. Building

on the synergies of Lean and Six Sigma, the chapter now continues by looking at its application in healthcare.

Table 2.3 Key points of review relating to Lean Six Sigma

Key point	Articulated by
Lean can be viewed as a coherent philosophy rather than just a toolset for change and improvement.	Syrett & Lammiman 1997; Moore, 2001; Bateman, 2002; Olexa, 2002a,b; Womack & Jones, 2003; Bhasin and Burcher, 2004; Liker, 2004; Kollberg et al., 2007; Aherne and Whelton, 2010; Graban, 2012; Williams, 2015, 2017.
Lean has evidenced improvement in healthcare settings.	Aherne & Whelton, 2010; Dodds, 2011; Jay, 2011; Graban, 2012; Jones & Woodhead, 2015; Teixeira Lot et al., 2018; Antony et al, 2019;
Kaizen originates in the Japanese management philosophy of harmony & loyalty, consensus in decision making, employment for life. These features are included in the Japanese concept of respect for people.	Imai, 1986 ; Suárez Barraza et al., 2011 ; Guimarães and de Carvalho, 2012.
Six Sigma is a statistical and data driven approach to change	Pande et al., 2002; Rath & Strong, 2002; Antony, 2004, 2007, 2008; George, 2005; Proudlove et al., 2008;
Six Sigma has a strong emphasis on eliciting and acting on the 'Voice of the Customer' and understanding customer expectations of service.	Antony, 2006; Langabeer et al., 2009; Antony, 2012.
Six Sigma has evidenced improvement in healthcare settings.	Pande et al., 2002; Rath and Strong, 2002; George, 2005; Laureani et al., 2013.
Lean and Six Sigma have demonstrable differences but also synergies in their approach to process improvement.	Vijaya Sunder (2013).
Lean and Six Sigma have had combined use in healthcare from 2002 onwards.	Lawal et al., 2014 ; Abu Bakar et al., 2015; Henrique and Filho, 2018.
Lean Six Sigma allows the synergies from each methodology to work in tandem for improvement.	Snee, 2010; Corbett, 2011; Gremyr & Fouquet, 2012; Vijaya Sunder, 2013.
Lean Six Sigma requires Critical Success Factors (CSF) to enable its successful use	Abu Bakar et al., 2015.

2.4 Lean Six Sigma in Healthcare

2.4.1 Introduction

Having introduced and discussed Lean, Six Sigma and their combined use as Lean Six Sigma, there now follows a discussion of its application in healthcare. Lean, Six Sigma and Lean Sigma have been in use in healthcare since 2001 in the UK and since 2002 in the USA and have become some of the most popular process improvement methodologies used in healthcare (Glasgow et al, 2010; Seidl and Newhouse, 2012; Burgess and Radnor, 2013; Teeling, Dewing & Baldie, 2020). The reasons attributed to the popularity of Six Sigma in healthcare include its attention to the needs of the customer (staff, patients and their families), quality, safety and a focus on viewing staff as customers in a process (Bohmer and Ferlings, 2006). The popularity of the use of Lean is reflected in Radnor's (2010) review of improvement methodologies for the National Audit Office in the United Kingdom that found that 51% of publications on process improvement focused on Lean (Radnor, 2010), and, of those, 35% were in the health sector (both hospital and community settings). In this next section, there is a discussion on the introduction of Lean Six Sigma and its use in healthcare with emphasis on approaches to implementation, the context of, and outcomes from, its successful use, and the strengths and weaknesses of Lean Six Sigma as a process improvement methodology.

2.4.2 The Evolution of Lean and Six Sigma Use in Healthcare

Although Lean Six Sigma is used as a combined approach to process improvement, the majority of papers concern the use of Lean or Six Sigma in healthcare independently, with a minority focusing on their combined use. A recent review of the empirical literature on Lean, Six Sigma and Lean Six Sigma (Henrique and Filho, 2018) found that of 74 papers on their use, Lean predominated (63%), followed by Six Sigma (22%) with Lean Six Sigma at 15%. This section draws on all relevant available literature to track the evolution of Lean Six Sigma in healthcare, referring to Lean, Six Sigma, or Lean Six Sigma as appropriate throughout. Burgess and Radnor's (2013) review of Lean deployment in NHS trusts found different approaches to Lean deployment, categorised as tentative, project-based, programme development and

systemic deployment across the organisation. Jones (2017) identifies four approaches to Lean deployment in healthcare (table 2.4).

Table 2.4 Approaches to Lean healthcare deployment

1.	Departmental approaches e.g. in Radiology, Pathology
2.	Whole hospital with a comprehensive management system; e.g., Thedacare in the USA (Toussaint, 2010)
3.	State-wide; e.g., Saskatchewan in Canada (Kinsman et al., 2014)
4.	DIY model with no use of external or internal consultants, managed internally with education and training delivered directly by front-line staff; e.g., the Spanish model developed in Barcelona at the quality-award-winning Consorci Sanitari Del Garraf (Jones, 2017).

Source: Adapted from Jones (2017)

Lean Six Sigma has been deployed in diverse contexts in healthcare, from acute hospitals to satellite hospitals, to primary care units (Vest and Gamm, 2009; de Souza, 2009; Graban, 2012; Graban, 2019). It is clear that as hospitals differ (e.g., in terms of geographical location, demographic profile of its catchment area, staffing levels and mix, specialisation and whether a local county hospital, an acute tertiary hospital or a community unit) context must be taken into account. However, Mazzocato et al (2010) suggest that there is little or no systematic research into how contextual differences are taken account of as Lean is deployed and implemented. In a review of eighteen studies on Lean use in Emergency Departments (EDs), Holden (2011) found that only one (Dickson et al., 2009) compared Lean use across hospitals.

In the UK, the concept of Lean Six Sigma in healthcare appeared in literature from the NHS Modernisation Agency in 2001 (Proudlove et al., 2008). Reports of Lean Six Sigma and improvements in the movement of patients (known as patient flow) as well as information, supplies and equipment between areas (Balogun, 2008) appeared in 2002 from a mid-sized hospital in the United States (US) (De Souza, 2009). Early

Lean healthcare leaders include the Virginia Mason Institute and ThedaCare in the US, Flinders Medical Centre in Australia with the NHS being an early adopter in the UK (Aherne and Whelton, 2010). Lean implementation in English hospitals and community trusts has become progressively widespread but is more commonly associated with larger hospitals. Fillingham (2007), who was instrumental in the development of Lean at the Royal Bolton Hospital Trust, sees the aim of Lean projects as improving clinical processes, identifying and eliminating waste from patient pathways, enabling staff to examine their work practices and increasing quality, safety and efficiency. Healthcare organisations are successfully using Lean thinking to streamline processes, reduce cost, and to improve quality and the timely delivery of products and services. Results have been captured and critiqued in academic journals (Miller, 2005; Kollberg et al., 2007; de Souza, 2009, Dickson et al., 2009). Early experiences from an Irish Hospital utilising Lean Six Sigma indicate that relatively novice users of Lean Six Sigma can create value for the organisation (such as reduced patient waiting times and increased staff satisfaction) in a relatively short period of time and in a variety of settings (Laureani et al., 2013). Laureani et al.'s (2013) paper is based on the experience of five masters students implementing Lean, Six Sigma or Lean Six Sigma as part of their course work and, although useful, exemplifies the lack of research into and publication of quality improvement reports focused on impacts from a range of perspectives, including the organisation, patients and their family, staff and organisational culture. Of significance, in relation to Lean Six Sigma deployment in Ireland, the literature before 2017 was predominantly on its use in the Central Statistics Office (CSO), with any healthcare literature again being limited to a single project or a single piece of work as distinct from an organisational level review. This indicates the lack of research into Lean Six Sigma at an organisational level in healthcare in the Irish setting, emphasising the need for this study. Some education programmes in Ireland have attempted to bridge the gap between single project and organisational level deployment by contextualising Lean Six Sigma within systems thinking frameworks (McNamara & Teeling, 2019).

In their report 'Fostering a Commitment to Quality' Hochman et al. (2016) reported the results of a series of interviews with management and staff in five of what they

considered to be ‘high-performing’ hospitals in the USA. The found that hospitals could achieve a ‘culture of quality’ by putting quality at the heart of their mission, by ensuring that all staff were cognisant of the need for quality and by asserting the primacy of the patient in all of their quality improvement initiatives. They found that all five of the hospitals they classified as high performing had adopted a Lean approach. The authors suggest that successful hospitals emphasise respect, an empowered frontline staff and data-driven processes to affect change and achieve desirable outcomes. Where Lean, Six Sigma or Lean Six Sigma has been utilised in healthcare settings, it has demonstrated certain specific successful outcomes (de Souza, 2009; Kollberg et al., 2007; Mazzocato et al., 2010; Yeh et al., 2011; Burgess and Radnor, 2013), which are have categorised at a high level into outcomes for the organisation, patients and staff (table 2.5). At a more detailed level, examples of specific successful outcomes for the customers (predominantly patients) from Lean Six Sigma deployment include:

- Reduced wait times and faster access to treatment in Emergency Departments (Fillingham, 2007; Cookson et al., 2011; Mazzocato et al., 2014);
- Improved patient outcomes in Cardiac Units (Laursen et al., 2003; McConnell et al., 2010, Ryan et al., 2019);
- Earlier access to diagnostics in Radiology Departments (Fillingham, 2007; Tolga Taner et al., 2007; Lodge and Banfort, 2008; Teichgräber and de Bucourt, 2012; O’Hora et al., 2015; Hynes et al., 2019);
- Streamlined nursing drug rounds on wards (Kieran et al, 2017);
- Redesigned controlled drug delivery processes releasing time to care (Abo-Hamad et al., 2012, Kieran et al., 2017, Creed et al., 2019);
- Reduced outpatient clinic waiting times both for appointments and in clinic (Cuevas and Joseph, 2015; Ryan et al., 2019).

Table 2.5 High-level view of Lean Six Sigma outcomes in healthcare

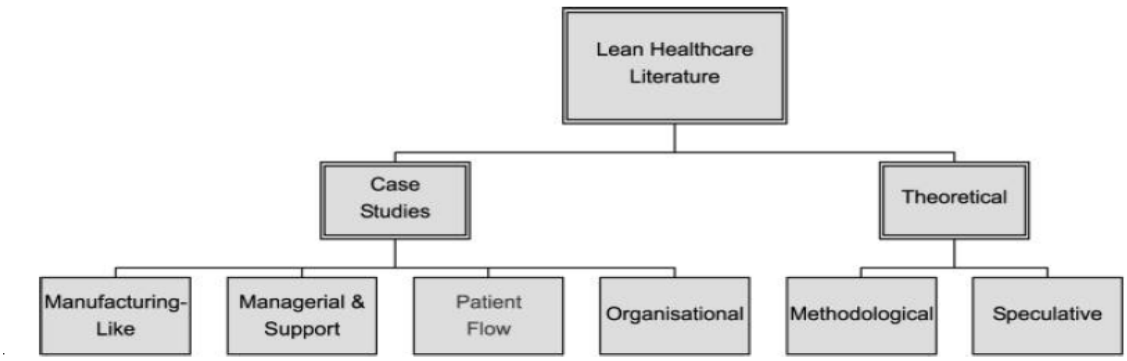
Organisational outcomes*	Patient Outcomes	Employee outcomes
Earlier admission	Satisfaction	Satisfaction
Turn Around times (TAT)	Mortality rate	Time to spend with patient
Arrival to Triage time	Readmission rate	Professional development
Wait time to physician	Informed	Reduced overtime
Consult wait time		Staff engagement
Discharge rates		
Length of stay		

*In relation to Key Performance Indicators (KPIs)

Source: Adapted from de Souza (2009); Kollberg et al. (2007); Mazzocato et al. (2010); Yeh et al. (2011); Burgess & Radnor (2013).

The high-level outcomes have been useful in informing the initial CMOcs, in conjunction with the context-setting Critical Success Factors, which were identified for Lean Six Sigma deployment (figure 2.5). De Souza (2009) shows that publications on Lean in healthcare (n=90) between 2002 and 2008 are either case studies (a description of real Lean implementation) or theoretical contributions (speculative translations of Lean into healthcare, and discussion on barriers for implementation) (figure 2.7). The studies vary from descriptive to highly theoretical. De Souza's review of the literature yields similar results to the first strand of this review (Lean Six Sigma in Healthcare: implementation and theory) (figure 2.1). It is evident that since 2009, there has been an increased focus on theoretical developments in systematic reviews of Lean and Six Sigma in healthcare (Aboelmaged, 2010, 2015; Burgess and Radnor, 2013; Andersen et al., 2014; De Koeijer et al., 2014; D'Andreamatteo et al., 2015; Deblois and Lepanto, 2016).

Figure 2.7 De Souza's taxonomy of Lean healthcare Literature
(n=90, 2004-2008)



Source: Taken from De Souza (2009, p.124)

In a review of peer-reviewed articles (n=162) on Lean Six Sigma deployment in management, business and healthcare disciplines between 2004 and 2014, Aboelmaged (2015) identified the distribution of Lean Six Sigma benefits and outcomes in healthcare, and identified the number of times each of the identified benefits was cited within the peer reviewed articles (figure 2.8).

Figure 2.8 Citation of Lean Six Sigma benefits and improvement in healthcare
(2004-2014)

Source: Taken from Aboelmaged (2015, p.233)

Aboelmaged reviewed each publication by year of publication, journal, area of

application, Lean Six Sigma tools used, benefits or improvements and type of research. He suggested categorising potential outcomes at three levels:

1. Patient and family
2. Staff
3. Organisational

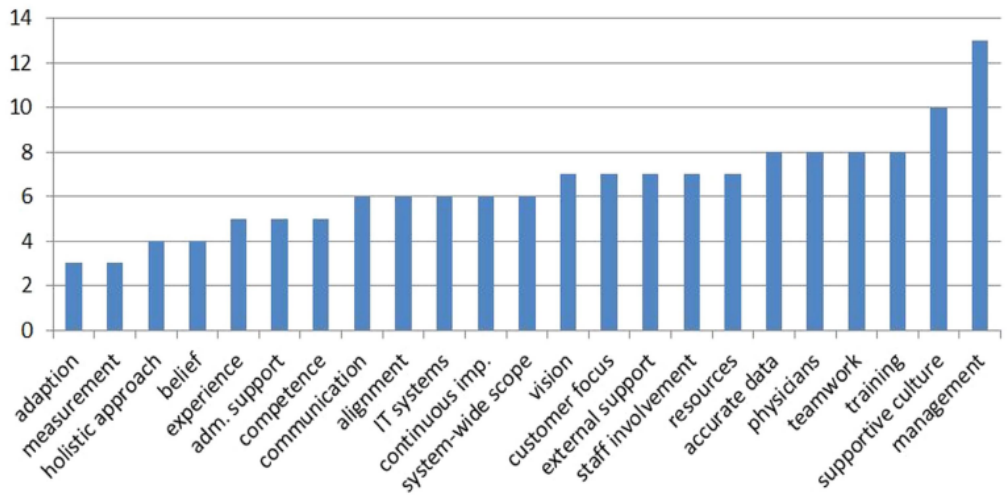
These outcomes are consistent with the high-level outcomes categorised in table 2.5 and have fed into the development of initial outcomes within CMOcs.

Although Lean Six Sigma is a popular methodology for improvement, it is still used in its component parts of Lean and Six Sigma, and even within this there is variation in the approach to deployment. Jones (2017) commented on the eclectic approach to Lean deployment, noting that some organisations go for a whole hospital Lean approach, whereas others apply only specific Lean tools. Where Lean is concerned with standardisation, it is interesting to note that Burgess and Radnor (2013) found some UK hospital trust managers are implementing Lean in a non-standardised way with wide variation in application, ranging from a cautious consideration based on learning from other hospitals, through to a more systemic approach aligned to strategy. According to Joosten et al. (cited in Waring and Bishop, 2010), Lean needs a robust evaluation that should include critical review from a theoretical perspective to see how it works with healthcare practices.

Having reviewed the literature examining the factors that facilitated Lean implementation, Andersen et al. (2014), and Andersen and Røvik (2015) claim that there is a lack of evidence to support arguments for the impact of Lean in healthcare such as increased access to services and improved patient outcomes. However, the literature previously categorised (table 2.5) from systematic reviews, indicates the positive outcomes from Lean and Six Sigma application in healthcare (de Souza, 2009; Kollberg et al., 2007; Mazzocato et al., 2010; Yeh et al., 2011; Burgess and Radnor, 2013) and the authors (Andersen et al. 2014; Andersen & Røvik, 2015) recognise that 'contextual preconditions' are a determinant of success, and also acknowledge that

how an organisation uses its resources and systems is a variable for success. This is consistent with other literature, where different organisations have had different degrees of success with their Lean, Six Sigma and/or Lean Six Sigma implementation. Andersen et al. (2014) conducted a realist synthesis of the Lean literature specific to hospitals from 2000-2012 following Prisma guidelines and identified facilitators of successful Lean implementation in eighteen hospitals (figure 2.9). They excluded papers where a hospital-wide focus was absent, single unit or department studies and the use of any combination of Lean and other quality improvement approaches.

Figure 2.9 Facilitators of Lean Implementation



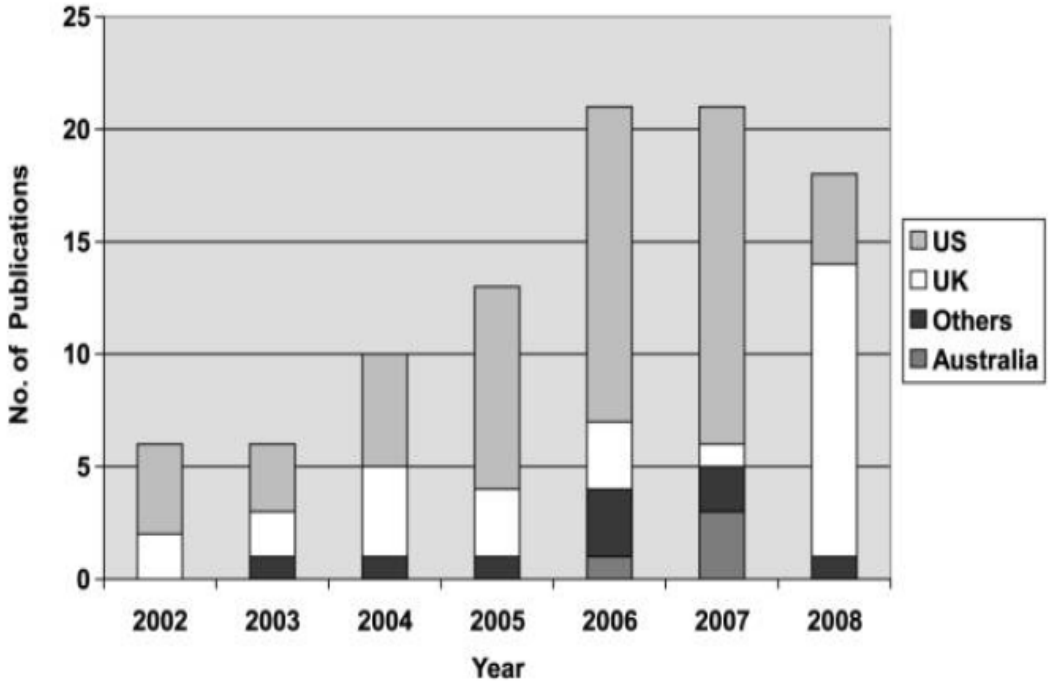
Source: Taken from Andersen, Røvik & Ingebrigtsen (2014, p.4)

The facilitators of Lean implementation (Andersen et al., 2014) (figure 2.9) concur with the Critical Success Factors identified by Abu Bakar et al (2015) (figure 2.5) and are discussed later in relation to the generation of this study's contexts in a CMOc. Black (2009) suggested that there is little literature about the challenges of, and failures in, the use of Lean, Six Sigma and Lean Six Sigma, with the focus being on success stories. However, since 2009 there has been an increase in the literature on Lean Six Sigma in a healthcare context that looks at the methodology at an organisational level rather than specific examples of success stories (Aboelmaged, 2010, 2011, 2015; Antony, 2012; Abu Bakar et al., 2015; McNamara & Teeling, 2019).

Vest and Gamm (2009) note that the literature contains many case, project or department-specific reviews on both Lean and Six Sigma, which lack good theoretical evaluation. Vest and Gamm (2009) conclude, however, that there are synergies among methods, with particular reference to Lean and Six Sigma as Lean Six Sigma. They recommend more rigorous examination of transformative process improvement and continuing dialogue between process improvement researchers and practitioners. Moraros et al. (2016) identified 1056 peer-reviewed articles on Lean, which, following screening for relevance to healthcare, yielded 22 studies. Of these, fifteen concerned process outcomes, with two showing a positive impact on existing processes. Three of the papers focused on process and health outcomes, with only one demonstrating a positive statistical benefit on both health and process outcomes. Of the four papers that focused on health outcomes, only one demonstrated that Lean had a statistically-significant impact. This highlights the importance of theoretical evaluation of process improvement methodologies such as Lean and Six Sigma.

In relation to Lean Six Sigma use internationally, De Souza's (2009) review of Lean in healthcare (figure 2.7) found that, based on the output of literature between 2002-2008 (figure 2.10), Lean appeared to be particularly popular in the US (57% of publications) and the UK (29% of publications). However, whilst the volume of publications increased year on year, it does not necessarily indicate an increase in the popularity of Lean, but rather increased interest in the results of its use. This interest will be of benefit if it leads to a more rigorous review of Lean use in healthcare settings that will continue to analyse the impact of Lean, Six Sigma and Lean Six Sigma use at the organisational, departmental and personal levels. This research into Lean Six Sigma will form a part of this ongoing analysis, which is particularly important in an Irish context, given its more widespread adoption in healthcare since 2013.

Figure 2.10 Lean healthcare publication output (UK, US, Australia, other), 2002-2008



Source: Taken from De Souza (2009, p131).

From a person-centred perspective it is important to remind ourselves of the importance of staff in any improvement process (Teeling, Dewing & Baldie, 2020). Aherne and Whelton (2010) and Graban (2012) suggest that, although healthcare delivery comprises myriad pathways, processes and sub-processes, it is not traditionally seen as process-orientated by healthcare staff who operate in what they see as a patient-orientated, problem-solving environment. This context and Black's (2009) observations that hospitals are 'complex social organisms' with added historical layers of power and hierarchy have been important to note in developing contexts for the CMOc. These social and behavioural aspects have made change management and process improvement implementation challenging in hospital settings (Black, 2009; Graban, 2012). This background makes staff engagement crucial to Lean Six Sigma deployment as for any change initiative as, ultimately, they are the people who will sustain any improvement (Huijsman et al., 2014; Proctor et al., 2015; Flynn et al., 2019). Flynn et al. (2019) stress the importance of contextual factors, suggesting that Lean improvement is best sustained where its deployment has

been adapted to the local context, with failure to do so impacting on sustainable improvement.

This section has discussed the introduction of Lean Six Sigma and its use in healthcare. It has looked at approaches to implementation, the context of, and outcomes from, its successful use, and the strengths and weaknesses of Lean Six Sigma as a process improvement methodology. Initial contexts include management commitment, leadership, organisational structure, competency of Black Belts, education and training and links to organisational strategy. The review has also identified outcomes for the organisation, the employee and the patient. Finally, it has also reviewed and discussed critiques of Lean Six Sigma. Lean Six Sigma is now discussed in the context of patients, staff and organisational culture. This more detailed analysis has allowed further refinement of initial findings in developing CMOcs for Lean Six Sigma in relation to person-centred care and person-centred cultures.

2.4.3 Lean Six Sigma and the Patient

For Womack and Jones (2003) the first step in implementing Lean thinking in healthcare is to put the patient in the foreground and include timely access to services in a safe and comfortable environment as key performance measures of the system. In Lean implementation Critical Success Factors such as medical quality, accessibility, comfort, treatment, respect and participation are of interest for specifying value from the patient perspective (Kollberg et al., 2007). Holden (2011) conducted a critical review of eighteen Lean implementation projects from fifteen Emergency Departments (EDs) in the USA, Australia and Canada. The Lean approach was shown to reform practice, streamline care-delivery and reduce unnecessary motion. Direct patient benefits included reduced wait-time and left-before-seen metrics, reduced length of stay and improved satisfaction. However, while patient experience improved, there was no evidence exploring its correlation with clinical outcomes. Martin (2014) suggests that healthcare is working at its best when the focus is both patient-centred and outcomes orientated. Mazzocato et al (2014) believe that the complexity of processes of care can either be enablers or disablers of Lean implementation. Their belief was based on a multiple case study over a period of four years of seven Emergency Department services (ENT, paediatrics, gynaecology, internal medicine

and surgery) using Realist Evaluation to identify mechanisms for how Lean impacts the ability of health services to learn and continue to improve. The study took place at a two-site tertiary academic hospital, the Karolinska University Hospital in Sweden, that serves a population of two million.

Mazzocato et al (2014) carried out realist interviews to link performance patterns to qualitative data. They found that the less complex care pathways yielded more improvement; however, for paediatrics, medicine and surgery, that have greater complexity (e.g. multiple core morbidities), change was harder to sustain. In their review of literature on Lean from 1998-2008, Mazzocato et al. (2014) identified literature (n=33) that helped identify components of successful Lean deployment. They included empirical studies of Lean application in healthcare and excluded articles not related to patient care. Four general components of Lean thinking in healthcare were identified, categorised as methods to:

1. Understand processes in order to identify and analyse problems.
2. Organise more effective and/or efficient processes.
3. Improve error detection and/or prevent harm from errors and pass information to people working on problems.
4. Approach change management and problem solving scientifically.

Each of these components was then identified as triggering a mechanism, referred to as a candidate mechanism. These candidate mechanisms were expanded by applying them to a case study of Lean implementation in Pennsylvania and yielded the following results:

1. How Lean and staff interact with each other (n=5)
2. Organisation of staff/staff competency (n=4)
3. How could staff/managers identify problems (n=7)
4. Care across organisational boundaries (n=1)
5. How care across organisational boundaries is organised (n=3)

Mazzocato et al. (2014) concluded that for Lean interventions to develop process capability, less complex pathways might be improved by building capacity to meet demand through improved staffing and staffing competencies. Lean Six Sigma and staff is discussed in section 2.3. For more complex pathways, Lean Six Sigma interventions must work across organisational boundaries. In relation to learning capability, the authors suggest that this must be fostered not just at the beginning of a process improvement journey but receive continuous support from senior management throughout. Mazzocato et al. (2014) conclude that the role that managers play in transformative Lean implementation and how senior management can promote process and learning capabilities requires further research. The role of managers in relation to Lean Six Sigma and organisational culture is discussed in section 2.4.5.

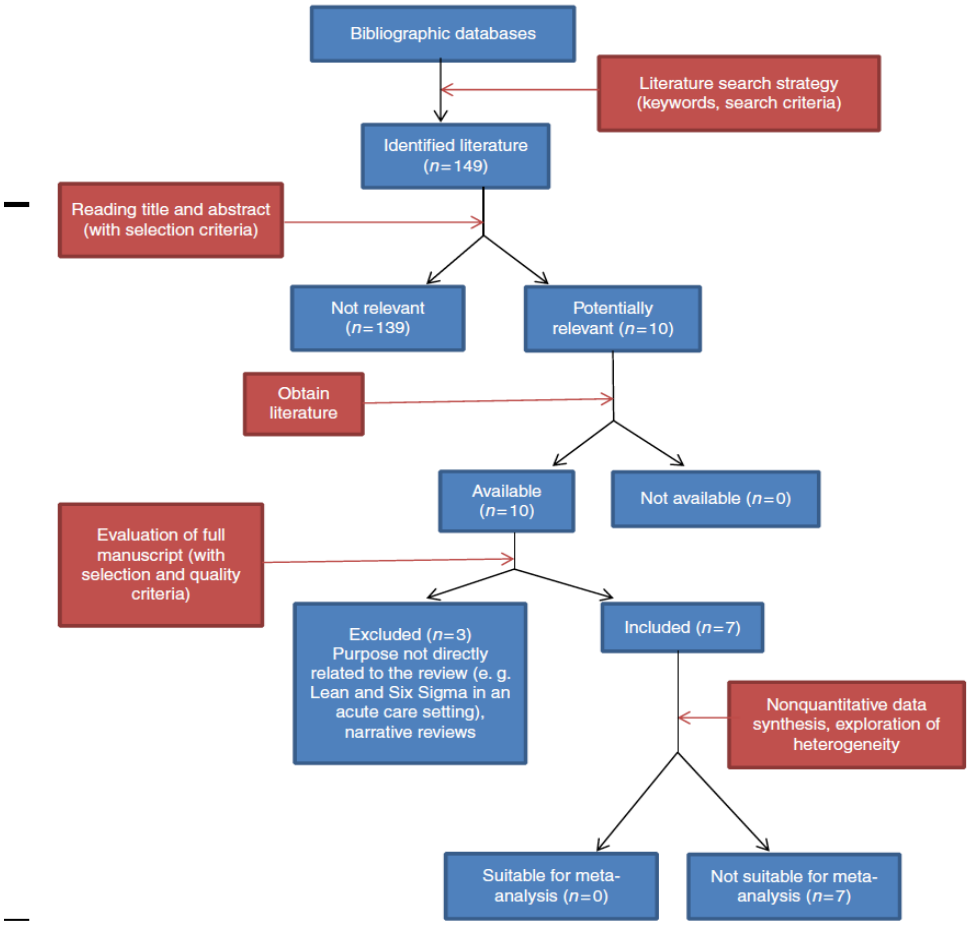
Williams and Radnor (2017) clearly demonstrate the links between the use of Lean principles and patient care pathways, illustrating the impact Lean-led improvement can have on the patient journey, if used appropriately and in the right context. The variation inherent in patient pathways includes factors such as age, presenting condition, prevalence of comorbidities (Health Service Executive, 2007), social circumstances and socioeconomic class; all of which can contribute to the complexity of care delivery. Williams (2015) suggests that more research is required on the complexity of healthcare pathways. Another issue is that busy hospital staff often work in departmental silos and don't see the entire service (Fillingham, 2007; Aherne and Whelton, 2010; Graban, 2012). Fillingham (2007) points out that the one person to see the entire patient journey is the patient. Byrne and Fitzsimons (2014) state, however, that families are often involved in patients' healthcare experiences and therefore their needs must also be included, as patients that have their support have better outcomes that often lead to lower costs for hospitals. From this literature review, it is evident that there are no evaluation studies of families' active inclusion in Lean Six Sigma projects. Predominantly, the literature looks at specific Lean, Six Sigma and Lean Six Sigma projects from the level of the organisation, staff and patient outcomes (table 2.5), with little reference to the role of families, although some more recent literature in Ireland has taken account of the role of families and carers (Loughnane et al., 2017; Ryan et al., 2019, Teeling et al., 2019; Connolly, Teeling & McNamara, 2020; Donegan et al., 2021).

Jones and Mitchell (2006) reviewed the application of Lean in Flinders healthcare in Australia and found that there were improvements in cost, the quality of care received by patients, service and staff morale. Jones and Mitchell (2006) suggest that implementing Lean principles elsewhere can bring similar benefits for patients and their families such as improved quality and safety, resulting in better overall care. Wiener (2004), conversely, argues that improvement methodologies with their basis in industry (such as Lean and Six Sigma) may not be suitable for healthcare and can actually detract from patient care by inadvertently redirecting clinician attention from patient care to administrative roles. However, this ignores the fact that Lean Six Sigma projects in healthcare are dependent on staff to invest and engage in projects and to have ownership of the implementation of their own solutions (Jorma et al., 2016) and sees them as developing and owning rather than merely administering solutions to problems.

In a systematic review of reviews of Lean, Six Sigma and Lean Six Sigma application in a healthcare setting (figure 2.11), Deblois and Lepanto (2016) found that three of the seven papers reviewed discussed using Lean Six Sigma, whilst three discussed Lean only, and one discussed only Six Sigma. The effects of all interventions using Lean, Six Sigma or Lean Six Sigma could be summarised as follows:

1. Five papers (71%) looked at specific health outcomes.
2. Seven papers (100%) looked at effects on the processes and quality of care.
3. Four papers (54%) looked at the economic benefits of improvement.
4. Five papers (71%) discuss patient and staff satisfaction.

Figure 2.11: Literature selection process for systematic review of reviews



Source: Taken from Deblois and Lepanto (2016, p.196)

It is notable that whilst there is feedback from patients (point 4) there was no patient involvement in any of the projects, and patient feedback could have been solicited in relation to processes of care (point 2). As noted, only three of the studies reviewed used a combined Lean and Six Sigma approach, although a main aim of Lean Six Sigma as a methodology is to eliminate variation and reduce errors to improve patient outcomes. However, this may be down to the requirements of the specific projects in the reviews, requiring either Lean or Six Sigma (George, 2003) and not Lean Six Sigma. It may also be attributed to the fact that as previously discussed, process

improvement practitioners may express a preference for either Lean or Six Sigma (figure 2.6). The review offers some information that has fed into the development of initial CMOcs on the identification of contextual factors critical to Lean, Six Sigma and Lean Six Sigma projects achieving their desired outcomes. These are identified in table 2.6.

Table 2.6 Facilitators and Barriers (contextual factors) to Lean Six Sigma from systematic review of reviews (Deblois and Lepanto, 2016)

Contextual factors that facilitate Lean	Contextual factors that can be barriers to Lean
• Engagement of staff	• Lack of healthcare qualified experts
• Engagement of management at all levels	• Staff education and training
• Recognised need for change by staff within the organisation	• Lack of focus on the patient
• Adaptation for local context	• Hierarchical structures within health care
• Recognition of the needs of the person not just the organisation	• Difficulties related to cross department collaboration
• A clear evaluation process present with organisational/ structural support	• Time pressure to allow for Lean adaption and incremental nature of projects

Source: Adapted from Deblois and Lepanto (2016)

According to Antony et al (2007), Lean Six Sigma enables the healthcare sector to deliver a high level of service to patients' only if the requisite Critical Success Factors are in place. Antony et al (2007) suggest these include:

1. Management support and commitment
2. Formation of Six- Sigma infrastructure
3. Staff education and training in Lean Six Sigma (so they can lead on their own projects)
4. Project selection

5. Communication
6. Organisational readiness (leadership and culture)
7. Leadership

At this point of this research, from the various reviews and studies, it is evident that there are some important critical success or contextual factors that influence the likelihood that Lean Six Sigma will have the desired impact of a positive influence on person-centred care and culture.

Applying Lean Six Sigma in healthcare settings has proven beneficial in mapping the patient journey to identify Non-Value Add and to improve care, and this has been demonstrated internationally in many clinical settings from Emergency Departments, to whole hospitals, to whole hospital groups (Womack et al., 2005; Ben-Tovim et al., 2007; Fillingham, 2007; Mazzocato et al., 2014). Lean Six Sigma projects in the study site that have been shown to have had an impact on patients (improved pathways for access to care) have now been reported in the literature:

- **Releasing time to care for nursing and pharmacy staff:** Reducing the duration of the 8am drug administration round by 50%, utilising Lean Six Sigma in a joint pharmacy and nursing project. Staff reported more efficient drug storage and organisation, and administration processes. Time freed up was 51 minutes now available for direct patient care (Kieran et al., 2017)
- **Reducing time for patient thrombolysis following stroke:** Reducing the median Door-to-Needle Time for stroke patients from 80 to 44 minutes, and the median door to CT time from 46 to 16 minutes by using Lean Six Sigma to develop a new stroke thrombolysis pathway (Feeney et al., 2016). This has resulted in patients (n=177) who follow the new pathway having rapid access to CT and subsequent diagnosis and treatment.
- **Improving process for Computed Tomography (CT):** Using Lean Six Sigma to improve CT Turn Around Time (TAT) from ordering of CT to final written result (O'Hora et al., 2015). Accuracy of reporting was improved by

61% in the first three months and a 20% improvement in TAT was noted. This meant earlier results and earlier diagnosis for patients.

- **Improving a hip fracture pathway:** A review of the hip fracture pathway in the study site to improve access of patients to the operating theatre and to the appropriate bed on the specialist orthopaedic ward (Murphy et al., 2019). The proportion of patients operated on within 48 hours improved from 62 to 79% with patient access to fascia iliac block for pain relief improving from 8.5 to 60%.
- **Improving access to nutrition and hydration for stroke patients:** Following a one-month pilot of a co-designed process for ensuring access to assistance at mealtimes, average wasted meals due to staff not being available to assist patients requiring mealtime assistance went from three per day to zero corresponding to an average reduction of 0.43 kg per participating patient in food waste per day. Patients receiving assistance did not require additional oral therapeutic nutritional supplements, evidenced no new incidences of aspiration pneumonia or swallowing difficulties and were discharged without requirement for ongoing dietetics and nutrition support (Teeling et al., 2019).

These peer -reviewed publications indicate a high level of staff engagement with and use of Lean Six Sigma at the study site.

This section has discussed how Lean, Six Sigma and Lean Six Sigma application in parts of the healthcare system can impact on patient outcomes through various interventions across all sectors of healthcare. These interventions can improve patient outcomes in areas as specialised as pathology, radiology, medicine, surgery, trauma, inpatient and outpatient care (Lighter, 2014). Examples of these improved patient outcomes have also been demonstrated in the literature relating to the study site (O' Hora et al., 2015; O'Toole et al.2016; Kieran et al., 2016; Hayden et al., 2016; Feeney et al., 2016; Kieran et al., 2017; Brown et al., 2019; Creed et al., 2019; Davies et al.,2019; Hynes et al., 2019; McGrath et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019). This section has facilitated identification of some contextual and mechanism- related factors from the literature which are influential in

realising outcomes, which link into the Critical Success Factors previously identified (figure 2.5). Throughout, the value of using Lean Six Sigma has been identified, in the analysis and redesign of processes of patient care in such a way as to ensure that the patient, and by extension, their families, are active participants in, rather than passive recipients of, the Lean Six Sigma projects. The impact of Lean Six Sigma on staff as reported in the literature is now discussed.

2.4.4 Lean Six Sigma and Staff

Gustavsson et al. (2016) suggest that, whilst the patient's view is paramount in determining healthcare quality, this is better served by also including the views of the healthcare professionals caring for patients who work within the system and know the culture. Jones (2017) suggests that what distinguishes Lean from other process improvement methodologies is its focus on developing the capabilities of teams (doctors, nurses, and administrative and support staff) to manage and continuously improve their work. When an organisation begins to adopt Lean, individual and team-based learning is the focus, not just in the classroom, but in the practice area. Jones (2017) argues that it is through this application of Lean that healthcare staff can remove unwanted Non-Value Add activities, giving them more time to spend with patients. Lean Six Sigma's interdisciplinary nature means that improvement projects can involve and engage team members across the healthcare community (Honda et al., 2018) such as nursing (Thomson, 2003; Collins, 2007; Fillingham, 2007; Nelson Peterson, 2007; Ballé, 2007), pharmacy (Sobek, 2003; Thompson, 2003; Miglani, 2015), pathology (Condel et al., 2004; Jimmerson et al., 2005; Zarbo & D'Angelo, 2007; Raab et al., 2008). O'Neill et al. (2011) suggest that nursing professionals are well placed as decision makers to identify and meet patient needs and argue that a bottom-up approach to process improvement works well. Lean Six Sigma utilises a bottom-up, top-down approach which means that healthcare staff are enabled to examine their own work processes, collecting and analysing their own data and implementing their own solutions (Jorma et al., 2016). According to Castle and Harvey (2009) this allows for rapid root cause analysis and genuine staff involvement, with staff leading on projects to improve patient outcomes. However, there is evidence in the literature that entrenched hierarchical structures and systems within healthcare as

well as professional and departmental silos can act as barriers to successful process improvement implementation (Ben-Tovim et al., 2007; de Souza, 2009; Mohd Amran et al., 2020).

Johnston et al. (2012) suggest that nursing is a profession ideally suited to Lean deployment as its members have extensive experience of working in and leading interdisciplinary teams, are patient focused and can view the healthcare system from the patient's viewpoint.

According to Graban (2012, p.1)

> Lean is an approach that can support employees and physicians, eliminating roadblocks and allowing them to focus on providing care. Lean helps break down barriers between disconnected departmental 'silos,' allowing different hospital departments to better work together for the benefit of patients.

Although not specific to Lean in a healthcare setting, the UK Institute of Personnel and Development, working with the University of Bath, published a report entitled 'The People Management Implications of Leaner Ways of Working' (Rees et al., 1996) that attempts to identify what constitutes Lean working practices, beyond the concept of Lean production. The authors report results from a study that investigated the human dimension of Lean systems and suggest that 'Leanness' is not an 'homogeneous or invariable state' but context dependent. These contextual factors in Lean application make it a process that requires adaptation to context, rather than a universally defined approach (Rees et al., 1996). Both Rees et al. (1996) and Syrett and Lammimam (1997) concur that 'Leanness':

1. Is context dependent
2. Can be perceived as a journey with a shifting final destination due to the focus on 'continuous' improvement
3. Is a dynamic but fragile system (within a system)

Lean projects are dynamic, changing in scope depending on the variables that they meet. For example, in developing a hip fracture pathway (O'Toole et al., 2016; Murphy et al., 2019), the project scope changed from the initial 'point of arrival to point of discharge' to a revised 'point of arrival to surgery'. This was based on the

context of the students carrying out the project having substantive posts and not having time to complete the initial scoped project. These are the types of contexts and variables in which Lean Six Sigma for healthcare operates. This was an important consideration in developing and analysing the initial CMOcs.

The impact of Lean on staff received early critique with Skorstad (1994) seeing Lean as meaning more work and a loss of autonomy. Delbridge and Turnball (1992) and Berggren (1993) focused on the impact of Lean on workers, with Lean production coined as 'mean production' and 'management by stress'. None of these criticisms relate specifically to the application of Lean Six Sigma in a healthcare setting but relate rather to an industrial setting. Holden et al. (2015) suggest that, when attempting to improve quality and generate efficiencies in healthcare, attention to the wellbeing, conditions of work and perceptions of staff is a priority. This not only benefits staff but recognises the influence of staff satisfaction on patient outcomes (Fahrenkopf, et al., 2008; Boorman, 2009., Kirwan et al., 2013; Carayon et al., 2013). Holden (2011) notes the lack of robust research into the impacts of Lean on healthcare employees. Holden claims that in almost every case the literature on Lean in healthcare discusses the outcomes of process improvement on patient care outcomes (Holden, 2011; Mazzocato et al., 2010; Poksinska, 2010) with few studies that consider the impact of Lean on staff, their attitudes to Lean or its effect on their work (Holden, 2011). However, some impact of Lean on staff has been captured in the literature reviewed:

1. Staff rather than management leading on improvement projects and initiatives (a bottom-up approach) leads to staff feeling empowered (Aherne, 2007; Deihl, 2011; Graban, 2012).
2. Staff actually having a say in the nature of and direction of improvement projects and initiatives, which also makes them feel empowered (Lipley, 2009).
3. Efficiency in daily processes having an impact on the patient outcome leads to staff satisfaction (Anthony, 2009).
4. Staff satisfaction with their engagement in improvement initiatives (Fine et al., 2009; Cima et al., 2011; Hydes et al., 2012).

Given the complexity of the healthcare environment and the continuous drive for improvement in service organisations there is the potential for staff to perceive Lean

and process improvement as another ‘fad’ (Seddon, 2011; McIntosh and Cookson 2012; Flynn et al., 2019).

In the UK, the Institute for Innovation and Improvement’s ‘Productive Series’, developed by the NHS in 2007 from Lean principles and methods, is the most prominent application of Lean in the NHS (Waring and Bishop, 2010) and may be the first experience staff have of it. From its inception in the NHS its use has spread to Europe, the US, Canada and New Zealand, launching in Ireland in 2011. The programme delivers thirteen modules for staff to help improve both the patient and staff experience and to release time for staff to deliver direct patient care. In a systematic literature review of the Productive Ward, Wright and McSherry (2013) found the programme had a positive impact on staff satisfaction in their job and on staff retention. Nursing staff also expressed their satisfaction with their ability to spend more time with patients. It is important to note that satisfaction with the Productive Ward programme does not necessarily suggest satisfaction with Lean. The Productive Ward utilises facets of Lean such as ‘5S’ (Visual Workplace Management) to create a work environment that is clean, well-organized and efficient (Womack and Jones, 1998), in the form of the Productive WOW (Well Organised Ward) module. 5S is a Lean tool, not Lean or Six Sigma, but a component tool, so satisfaction with the 5S aspect of the Productive Ward does not indicate staff had a positive experience of Lean or Six Sigma.

White et al. (2013) in a review of the impact of both the productive ward programme and Lean on employees (n= 108 papers) identified the following impacts on employees who participated in either Lean or Productive Ward initiatives:

- Empowerment
- Leadership
- Engagement

Whilst this seems positive in regard to Lean’s impact on employees, the review acknowledges that we must take into account the many variables and contexts involved in the nature and location of the Lean studies.

To engage staff in Lean Six Sigma, it is essential that they have ownership of the process improvement initiative, not just as a means to an end, but as an end in itself (Bushell et al., 2002; Sirio et al., 2003;Bahensky et al., 2005; Endsley et al., 2006). Spear (2005) argues that Lean enables people at all levels of an organisation to become 'experimentalists', learning how to improve the work they do. Womack et al (2005) suggest that healthcare workers traditionally see themselves as working in a particular department or on a particular team, in effect in functional silos. Drotz and Poksinska (2014) claim that one of the main barriers to Lean implementation is staff's disbelief that Lean can apply to healthcare. This can lead to initial responses to process improvement along the lines of this is the 'the way we've always done it' (Graban, 2015), 'that's not how we do things here' (Del Marmol, 2018) or 'we've tried it before and it didn't work' (Roussel, 2019). Aherne and Whelton (2010) suggest that, as with any change initiative, Lean will not work without the first step of educating the workforce about what it actually is and how it works.

Dickson et al. (2008) propose that healthcare staff will relate to process improvement better if trained by other healthcare staff who are improvement experts, rather than the usual over-reliance on industry consultants. Jones and Woodhead (2015) similarly suggest that the development of process improvement skills is best 'nurtured and sustained' by colleagues acting as mentors or coaches and not by delegating the implementation of improvement to external or internal consultants, which staff viewed negatively (Flynn et al., 2019).

Jones and Woodhead (2015) reiterate that Lean skills are learned through daily practice and not just from classroom training in Lean tools or occasional workshops. Joosten et al. (2009) believe that managers must focus not only on process improvement, but also on developing their staff through support, respect and education, as ultimately it is the staff who will implement any change process.

The Toyota Production System (TPS) that underlies Lean thinking supports the concept of a customer focus with employee involvement and committed support from leadership (Dahlgaard-Park, 2011; Spear & Bowen, 1999). However, the application of Lean Six Sigma in industry and the civil service has been heavily critiqued for its adverse impact on staff from a humanistic viewpoint, emphasising the lack of potential

for innovation and the poor quality of the work environment for workers attempting to meet efficiencies (Stewart et al., 2009; Mehri, 2005, 2006; Carter et al., 2013). Conversely, Ballé and Regnier (2007) feel that staff empowerment and a culture within the organisation which encourages improvement are the cornerstones of the approach to Lean in healthcare.

According to Drotz and Poksinska (2014), in a paper based on three cases studies of healthcare organisations regarded as successful examples of Lean deployment, core job characteristics for staff in a Lean environment are skill variety, increased task identity, use of feedback, decentralised decision-making, responsible autonomy, and work facilitation where barriers to flow are removed. Drotz and Poksinka's (2014) study used literature review, document review, observation and interview. They found that by committing fully to appropriate training and use of Lean, process changes had led to positive effects for staff with respect to their working environment, individual development and overall performance. Cross-professional teamwork decreases 'hierarchical structure and boundaries between professional groups' (Drotz and Poksinska, 2014, p. 191) and the authors found that employees appreciate the increased responsibilities and autonomy.

As with any change initiative, Lean can be disruptive, 'asking people to change what they do and how they do it can be very unsettling' (University Medical Centre Groningen [UMCG] 2014, p. 7). People can understandably be nervous, and even defensive about any change (Aherne & Whelton, 2010; UMCG, 2014). In Saskatchewan, Canada, where what is considered to be the largest Lean implementation in the world has taken place (Kinsman et al., 2014), staff satisfaction with the process and impact of Lean deployment was considered an important outcome for evaluation. Moraros et al. (2016) detail how a random sample of nursing staff (n=1500) across the province surveyed by an external polling agency on behalf of the Saskatchewan Union of Nurses indicated that 58.2 % of nursing staff surveyed said morale had declined since the introduction of Lean, 7.8% said morale had improved and 34% saw no change (Saskatchewan Union of Nurses, 2014). This survey, whilst subject to the potential bias of being carried out by a union, did have a 100% response rate (n=1500) and indicates that Lean does not necessarily have a positive impact on

staff morale. The intense push of the Lean improvement (Moraros et al., 2016) may in part explain the survey results. Many simultaneous changes may become stressful for employees (Forrester, 1995; Sawhney & Chason, 2005) and cause change fatigue in the face of multiple change initiatives (Wanous et al., 2000). According to Falkenberg et al (2005), employees perceive change to be excessive in two situations:

1. When several conflicting change initiatives are simultaneously implemented (e.g. Lean Six Sigma, new falls prevention protocols, quality walks, new regulatory guidelines)

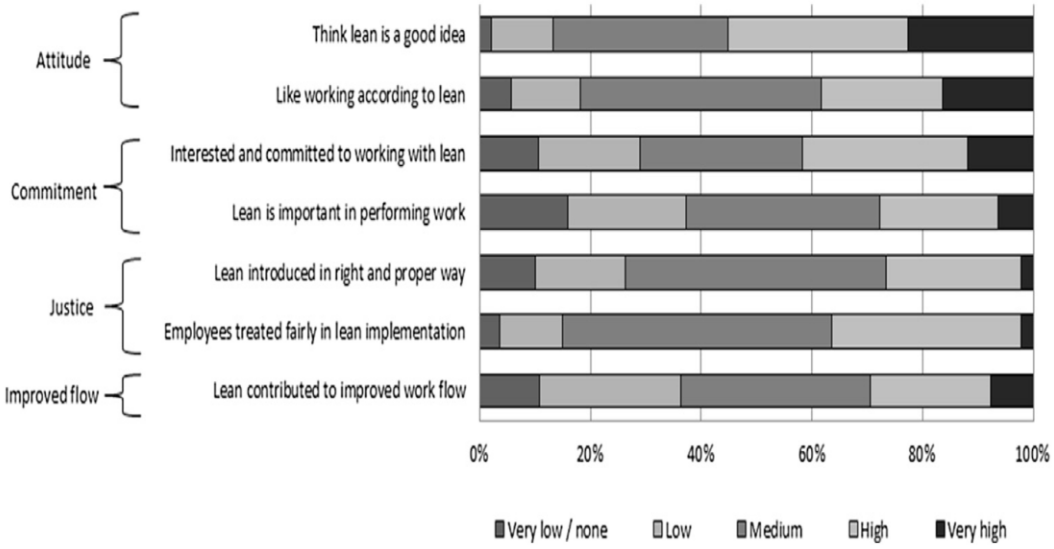
2. When new changes commence before previous initiatives or projects are complete (e.g. starting a new Lean Six Sigma project before another is completed, leading to more change than employees can 'handle' at one go).

Fine and Golden (2009) advise that healthcare staff should not be threatened by the Lean philosophy; it is not about 'shedding staff', but about eliminating waste in all tasks and processes. There have been discussions about Lean Six Sigma use reducing overtime (Antony et al., 2007; Tolga Taner et al., 2007) as distinct from 'released' staff time. Based on thirteen case studies from the UK, Ireland, the US, Canada, and Brazil, Aherne and Whelton (2010) suggest that by removing waste from daily work, valuable resources, including staff, can be utilised to their full potential. By focusing on 'value' to the customer, or patient, staff can direct more time and effort towards patient care. However, the literature fails to focus on the negative impact on staff when this redirecting of resources does not occur, causing frustration and cynicism. Wanous et al. (2000) suggest that one of the prime components of cynicism are negative beliefs about the likelihood of a change initiative's success. This study will elicit the perceptions of staff at the study site of Lean Six Sigma deployment.

In Sweden, both Lean and Six Sigma are used in healthcare; however, most of the literature refers to their individual rather than combined use. Lean deployment is required in the public sector, which includes healthcare organisations. Weimarsson (2011) reported that 90% of Swedish public hospitals had utilised Lean; however, as there is no model or plan of deployment, each hospital is free to develop its own model (Hines et al., 2004). There is therefore huge variation in the use of Lean in Swedish

healthcare. Holden et al (2015) look at perceptions of Swedish healthcare staff in three hospitals across varied contexts such as hospitals, and high and low acuity units, and professional roles (nursing and medicine). The variation in feedback from staff, aggregated from all three hospitals, wards/units and professions is shown in figure 2.12. This illustrates how staff ranked their experience of Lean from very low (worst) to very high (best) under the themes of attitude, commitment, how lean was introduced (justice) and impact on flow. Whilst 33% of staff perceived improvement in clinical practice and had a positive outlook on Lean, others reported dissatisfaction. The study found that the context variables of hospital, unit and clinical role accounted for 10-20% of the variance in perceptions of Lean. This study and its findings are of importance, as they are an excellent example of how context influences attitudes to Lean deployment and has also identified potential mechanisms that enable Lean (management support, education, experienced educators and facilitators).

Figure 2.12 Employee Feedback on Lean in Three Swedish Hospitals



Source: Taken from Holden et al. (2015, p.24)

A study on the first large scale deployment and use of Six Sigma in Sweden (Lifvergren et al., 2010) between 2006-2008 reported that Six Sigma was considered to be a useful methodology for improving healthcare processes. The study reviewed the first 22 Six Sigma projects at the Skaraborg Hospital Group and found that, among

projects using Six Sigma, there was a 75% success rate in achieving intended goals within eighteen months. The study also reports that that Six Sigma was recommended as an addition to the other improvement methodologies used in Swedish healthcare such as Lean. Today, the Skaraborg Hospital Group uses a combined Lean Six Sigma framework with staff educated and trained in Lean and Six Sigma supporting other staff in their ongoing process improvements.

Returning to the philosophy of Kaizen, in healthcare Kaizen tends to focus on the more active principles and methods of daily improvement, such as Rapid Improvement Events (RIEs) or Kaizen events, week-long collaborative process improvement events. However, according to Suárez Barraza et al. (2011), this short and intense focus on process improvement can ignore the individual and personal principles underpinning the concept of Kaizen, which require attention to employees' working and social lives. In order to incorporate the 'person' aspects of Kaizen, some healthcare institutions such as Thedacare and the Virginia Mason Medical Center in the US have developed comprehensive management systems based on Lean and/or the Toyota Production System (TPS). The two pillars of the original TPS or the 'Toyota way' were continuous improvement coupled with respect for people (Toussaint & Gerard, 2010). This link to the concept of Kaizen is important. Thedacare aims to become the healthcare employer of choice by focusing on respect for people and has developed a 'human development value stream' to involve staff and create leaders with all the abilities to drive process improvement.

However, Thedacare refers predominantly to 'Patient-centred Care' and has a focus on improvement with the patient at the centre of their principles for healthcare with no mention of staff. For example, Toussaint and Gerard (2010) translate Thedacare's principles for healthcare as: (1) patient focus; (2) care design around the patient; (3) identify what is Value Add for the patient; (4) eliminate Non-Value Add; and (5) reduce time factors e.g. appointment time, treatment time. This does not imply a lack of staff involvement or respect for staff but suggests a patient as distinct from a person-centred approach. For Toussaint (2015), key elements in a Lean transformation process are establishing values and principles of patient first, respect for others, consensus on expected behaviours and leadership, and having a no-blame culture. In the literature

reviewed, studies on the application of organisational Kaizen in Japan and other countries in the East were limited to large organisations and non-healthcare multinationals (Tanner & Roncarti, 1994; Cheser,1994 1998; Brunet and New, 2003).

Imai (1986) sees Kaizen as involving employees in practices that enable them to incrementally identify and suggest ideas for improvement on an ongoing and sustainable basis. There is a wider application of the principle of respect for people, which refers not only to their involvement in work process but also to their wellbeing and work-life balance. Mazzocato et al. (2016) looked at process improvement suggestions (n=186) from interdisciplinary staff (n=165) collected over a year in a Swedish hospital, with data analysed and classified independently by two researchers and disagreements checked by a third researcher. A limitation was the lack of interviews or focus groups with staff. Seventy-two percent of the process improvement suggestions were reactions to problems perceived by the staff, which included visual management issues that took up staff time (such as those identified and addressed in the Productive Ward series). There was little emphasis on socio-technical issues such as staff creativity and staff wellbeing. Mazzocato et al. (2010; 2016) suggest that there is a need for Kaizen to embrace employees' viewpoints to a wider extent than suggestion forms and boxes. Mazzocato et *a*l (2016) conclude that within healthcare organisations there is a need to develop Kaizen practice not just with clinical and support staff but at the management level.

In this section Lean Six Sigma has been discussed in the context of the involvement of, and impact on, healthcare staff. Papers examining feedback from staff on the use of Lean, Six Sigma and Lean Six Sigma have been reviewed, themes identified, and the concept of Kaizen use in healthcare discussed. The discussion has highlighted the importance of context in Lean Six Sigma application and the significance of identified mechanisms, such as management support, education, experienced Lean Six Sigma educators and facilitators, for enabling Lean Six Sigma acceptance, use and ownership by staff. The literature also speaks to the involvement of the entire organisation in Lean Six Sigma, and this is now discussed in the context of organisational culture.

2.4.5 Lean Six Sigma and Organisational Culture

Managers of healthcare organisations face the unenviable task of working with limited resources (Foshay & Kumziemsky, 2014) to deliver high quality care. Organisations face pressure to sustain a quality service and deliver change while achieving operational and strategic excellence and keeping the service patient focussed (Gabutti et al., 2017). From a purely business perspective, Six Sigma could be described as a means to improve the profitability, effectiveness and efficiency of all operations to increase customer satisfaction (Kwak & Anbari, 2006). Healthcare may be run as along a business model (Sharan et al., 2016) but as long as this model seeks to deliver value to the customer, patients and their families, this is not necessarily a bad thing. Additionally, the goal of Lean Six Sigma in healthcare is to move from the current state to a future, more productive state. In order to achieve this, Tolga Taner et al. (2007) believe that top management must select quality initiatives that tie projects to organisation goals and identify meaningful performance metrics.

Moving away from a purely business perspective, Radnor and Boaden (2008) claim that Lean deployment is dependent on a number of variables, one of which is organisational readiness for Lean application. Lean works and becomes embedded in organisations when we put the patient first (Mazzocato et al., 2010; Kaplan et al., 2014; Ulhassan et al., 2014). However, Arthur (2016) outlines the importance for management of also engaging staff, identifying the early Lean Six Sigma adopters, and inspiring the team through open communication and support. As previously discussed, by listening to the 'Voice of Customer' (patients, staff and relatives) and tuning the 'Voice of Business' to this wavelength, organisations can develop a shared vision that has the patient as the focus of all activities. Healthcare organisations must lead with care (Fillingham, 2007; de Souza, 2009), with the commitment to Lean starting at the very top of the organisation (Womack et al., 2005; Kaplan et al., 2014) and leaders must create a culture that is receptive to Lean thinking (Womack et al., 2005). It is not just top but middle management who must support the concept of a Lean organisation (Manville et al., 2012; Clark et al., 2013; Toussaint & Berry, 2013) in order to facilitate organisational change. Andersen et al (2014) suggest that the most important enablers (n=23) of Lean deployment in an organisation are a top-down *and* bottom-up approach

with support from management and the engagement of teams of clinicians and other staff in a supportive culture. Management is seen to have a supportive role in the implementation of any Lean initiative, facilitating, educating and empowering teams to apply Lean tools (McFadden et al 2015). Antony (2017) reiterates that Lean Six Sigma needs management support, education and training. Mårtensson et al. (2019) suggest that increasing management knowledge through education and training in Lean is a route to increasing the sustainability of Lean Six Sigma interventions. Sustainability requires a whole-organisation approach with the use of Lean principles by front-line staff supported by management with training in Lean Six Sigma.

Focusing intently on the tools and techniques of Lean and Six Sigma alone, however, may mean that contextual factors like 'leadership' and 'organisational readiness' are not given adequate attention (Burgess & Radnor, 2013; Laureani & Antony, 2017; McNamara & Teeling, 2019). The embedding of Lean Six Sigma may require internal organisational and educational infrastructure and the development of in-house experts (e.g. Black and Green Belts) (University Medical Centre Groningen, 2014). The concept of in-house Lean expertise was seen as a mechanism for embedding Lean Six Sigma in Finland where employees working in one healthcare organisation (n=79) indicated that 84.5% of hospitals had trained in-house Lean experts (Jorma et al., 2016).

Lean has been described as entailing a five to ten year journey with milestones (Hines et al., 2008), leading to gradual cultural and behavioural change (Burgess & Radnor, 2013) with care pathways to improve patient outcomes redesigned by staff who are supported in the redesign. Hines et al. (2020) see Lean as a lifelong journey, continually coaching and developing staff. Toussaint and Berry (2013) suggest that Lean is transformation at a cultural level. Therefore, a long-term vision of transformative change is necessary to enable staff to work across functional divides (Kollberg et al., 2007; Burgess and Radnor, 2013). According to Dickson et al. (2009), the level of continuous leadership commitment to Lean affects the outcomes of Lean Six Sigma Projects and their sustainability. Waring and Bishop (2010) suggest that although Lean Six Sigma is reliant on continuous leadership commitment, it actually also lends to distributed leadership through Lean champions and Lean educators.

Meaningful staff engagement by management, training front line staff and forming effective teams are all part of this process of culture change. Lean deployment in healthcare organisations is not just about quality improvement but is part of an overall organisational strategy that links to institutional culture and focused leadership (Kaplan et al., 2014). McCormack et al. (2011), speaking to the development of cultures to support person-centredness, note that current organisational culture and the environment of care itself pose the greatest challenge to culture change. To sustain Lean and improvement methodologies, healthcare organisations must foster 'a strategic climate, which focuses the shared perceptions of employees on quality, efficiency and innovation' (Huijsman et al., 2014, p. 2911).

Knapp (2015) examined Lean Six Sigma implementation in hospitals and the hospitals' culture. The study involved 104 hospitals and found that managers who emphasised group culture were more likely to initiate a successful quality improvement initiative. Factors such as collaboration, involvement and learning are found to be essential to the implementation of Lean Six Sigma, which links to the findings (section 2.3) on staff attitudes to Lean Six Sigma. Knapp's (2015) study also found that hierarchical structures (controlling and rigid) had significant adverse impact on Lean Six Sigma deployment and that control orientated rational cultures (achievement and results-focused) likewise impacted on staff interaction with Lean Six Sigma interventions (Knapp, 2015). A limitation in Knapp's (2015) study is that only two staff members per hospital were included, a quality manager and a human resources staff member; these individuals may have been biased, viewing quality as important and wanting to present a positive image. Knapp's (2015) work suggests that an emphasis only on process improvement in Lean Six Sigma can lead to criticisms of a lack of focus on people (staff and patients). However, it also illustrates that a collaborative approach requires a focus on persons (patients, their family and staff) as well as processes.

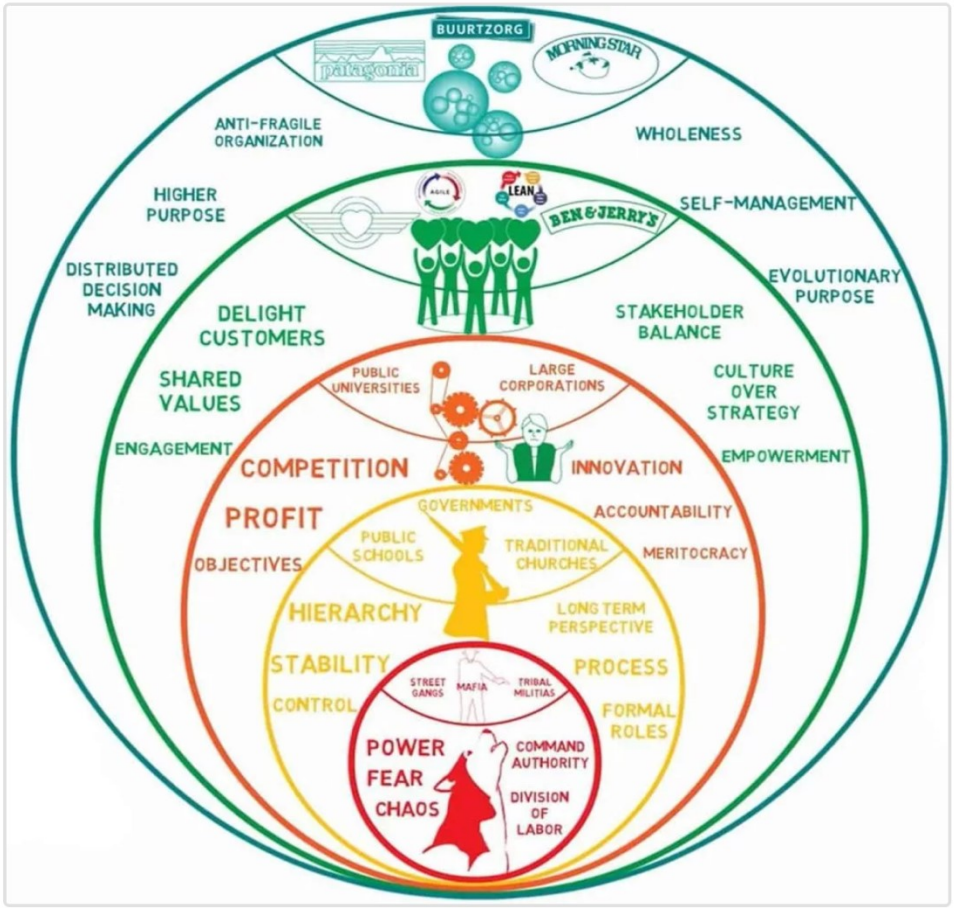
An ethnographic study of Lean implementation in an NHS Operating Department over a twelve-month period by Waring and Bishop (2010) led the authors to conclude that Lean might not be an easy 'remedy' for making improvements in healthcare effectively. However, it should be noted that Operating Departments are acknowledged to be silos (Cumin et al., 2013) with a traditional uni-professional 'silo

mentality' (Bleakley et al., 2006). This requires work on how best to overcome the barriers to implementation of any interdisciplinary team training (not just Lean Six Sigma). Tsasis and Bruce- Barrett (2008), on the other hand, believe that organisational change and healthcare improvement can be achieved with Lean thinking, as from a Lean viewpoint, the organisation is viewed at a process level as comprising multiple and collective processes pursuing a common goal. A Lean approach which is cognisant of the original concepts of Kaizen and with a focus on person-centredness could provide a robust model for organisational change.

Deming (2000) suggests that best practice is for management to manage organisations as systems that encourage continual learning and advancement. This effectively negates silo thinking 'where people have lost hope of ever understanding the relationship of their work to the work of others, yet do not talk to each other' (Deming, 2000, p.29). Jones and Woodhead (2015) suggest that supporting process improvement presents new challenges for senior management within organisations, concluding that managers need to spend time talking to staff, understanding their concerns and issues, and offering support by asking questions rather than telling staff what to do.

Laloux (2014) discusses how new perspectives and practices have evolved over the centuries in organisations as large groups of people live and work together. These perspectives or paradigms are classified by Laloux by their characteristic ways of being, thinking and doing, and are colour-coded (figure 2.13). A teal organisation is seen as self-managing as opposed to hierarchical, metaphorically organic. A green organisation is viewed as focused on a culture of empowerment, metaphorically, a family. An orange organisation is metaphorically described as machine-like and competitive with a command-and-control approach to management. An amber organisation manages with a top down command-and-control approach and is likened to an army. Finally, a red organisation is viewed as chaotic and highly reactive and is metaphorically a wolf pack.

Figure 2.13 Laloux's Organisational Paradigms



Source: Taken from the reinventing organisations website (Laloux, 2014)

Laloux (2014) suggests that Lean originated within the Green paradigm, which focuses on culture, empowerment and employee motivation. Breckenridge et al. (2019), discussing humanising process improvement, highlight motivational processes as central to any change or improvement initiative, with an emphasis on listening to individuals. Organisations which are Green are values driven, engage stakeholders and are consensus orientated. This is an interesting analysis as it emphasises the less operational aspects of Lean and focuses on the 'respect for people' approach with consensus seeking and empowerment. However, Laloux advises that when consensus building is protracted, hierarchical structures and attitudes may emerge from the Orange paradigm, which Lean may straddle. If managers operate from an Orange perspective, they will have a command-and-control approach and will view Lean only

as a process improvement activity. According to Laloux (2014), this ignores the culture and empowerment emphasis of the Green paradigm and leads to top-down management.

2.4.6 Summary

This section has contained a discussion on Lean Six Sigma in healthcare in relation to patients, staff and organisational approach (table 2.7). The positive attributes of Lean Six Sigma use and their impact on patient outcomes and staff morale have been illustrated. However, it has also been shown how Lean Six Sigma, when used in a reductionist way, can focus on the improvement and not on the people: staff, patients and relatives. This is a move away from the original Japanese concept of Kaizen, which as discussed, may be useful in the development of person-centred cultures. There has been further insight into the importance of the context of use of Lean Six Sigma and the mechanisms which may contribute to its success or failure in organisations. Based on this knowledge, there is an awareness of the potential pitfalls of a reductionist approach to both Lean and Six Sigma, and the likely failure if delivered as a command and control process improvement. Without mechanisms such as senior leadership commitment and support, strategic oversight, widespread education and training of staff and qualified in-house facilitators (Schattenkirk, 2012), a process improvement which is built upon 'respect for the person' will not be achievable. The next section moves on to discuss person-centredness and how Lean Six Sigma may contribute to person-centred cultures.

Table 2.7 Key points of review relating to Lean Six Sigma in healthcare

Key message	Articulated by
Lean can be deployed in different ways categorised as tentative, project based, programme development and systemically.	Burgess & Radnor, 2013.
Lean can be deployed at different levels including departmentally, whole hospital, statewide and by internal or external staff.	Jones, 2017.
Lean Six Sigma has been deployed in diverse healthcare contexts, with sustained improvement best achieved where adapted to local context.	Vest & Gamm, 2009; de Souza, 2009; Graban, 2012 ; Graban, 2019., Flynn et al, 2019.
Contextual factors can be facilitators or barriers to Lean Six Sigma deployment.	Radnor et al., 2012 ; Deblois & Lepanto, 2016.
A key variable for Lean deployment is organisational readiness.	Radnor and Boaden, 2008; Radnor et al, 2012.
Lean Six Sigma has evidenced improvement in healthcare settings at patient, staff and organisation level.	Fillingham, 2007 ; Ben Tovim et al., 2007 ; Kollberg et al., 2007 ; de Souza 2009; Mazzocato et al., 2010 ; Cookson et al., 2011 ; Yeh et al., 2011 ; Burgess & Radnor, 2013 ; Lighter, 2014 ; Aboelmaged, 2015.
Lean, Six Sigma and Lean Six Sigma in healthcare continue to grow in popularity internationally with a corresponding increase in publication.	de Souza 2009 ; Moraros et al., 2016.
Lean Six Sigma specifies value from the patients perspective and results in direct patient benefit.	Womack &Jones, 2003; Jones & Mitchell, 2006; Kollberg et al., Holden, 2011; Williams & Radnor, 2017.
Critical Success Factors (CSF) for Lean Six Sigma include Management support, infrastructure, staff education and training, project selection, organisational readiness and leadership.	Antony et al., 2007.
Lean Six Sigma can involve and engage team members across the healthcare community, including their voice in achieving continuous improvement and developing them as individuals.	Imai, 1986 ; Thomson, 2003; Collins, 2007; Fillingham, 2007; Nelson Peterson, 2007; Balle, 2007 ; O'Neill, 2011 ; Graban, 2012 ; Jorma et al., 2016 ; Jones, 2017; Honda et al., 2018.
Staff are engaged when they have ownership of process improvement and are educated, trained, nurtured and sustained by other internal healthcare staff who are proficient in Lean Six Sigma.	Bushell et al., 2002; Sirio et al., 2003;Bahensky et al., 2005; Endsley et al., 2006 ; Dickson et al., 2008 ; Jones & Woodhead, 2015 ; Jorma et al., 2016 ; Flynn et al., 2019.
Kaizen practice embraces employees viewpoints.	Imai, 1986; Mazzocato et al., 2010, 2016 ;

Lean was developed with a focus on culture, empowerment and employee motivation.	Laloux, 2014.
There can be a tendency for healthcare practitioners to view Lean at the level of a set of improvement tools rather than as a philosophy.	Burke, 2008; Radnor et al., 2012; Suárez Barraza et al., 2011; Stone, 2012; Burgess & Radnor, 2013.
A focus on Lean Six Sigma tools and techniques ignores important contextual factors such as leadership, organisational readiness and transformation at a cultural level.	Burgess & Radnor, 2013; Laloux, 2014; Kaplan et al., 2014; Laureani & Antony, 2017; McNamara & Teeling, 2019, Teeling, Dewing & Baldie, 2020.

2.5 Person-centred care and Person-centred Cultures

2.5.1 Introduction

This section discusses the concepts of person-centred care and person-centred cultures in relation to the healthcare environment and how they may be influenced by Lean Six Sigma. It is important to understand the concepts of person-centred care and person-centred cultures in order to discern their relationship to Lean Six Sigma and to ascertain any influence Lean Six Sigma has on person-centred cultures. Literature is reviewed to explore the impact of person-centred care on an organisation's processes and cultures. Sanderson and Lepkowsky (2003) see a person-centred organisation as one that uses person-centred practices to deliver shared visions and values. How person-centred care can flourish in a culture of targets and Key Performance Indicators (KPIs) is a key topic, and the synergies with, and divergences, from, Lean Six Sigma will be explored.

2.5.2 Defining Person-centred Care in Healthcare

McCormack (2004) has developed a model that identifies four key components of person-centred nursing; however, the components, he argues, can be applied to person-centred care provided by any healthcare professional. They are:

1. Relationships. The relationship between the nurse and the patient is critical to positive outcomes.
2. Social world. The ability to adapt the context of care to create a caring environment suitable for the patient's needs.

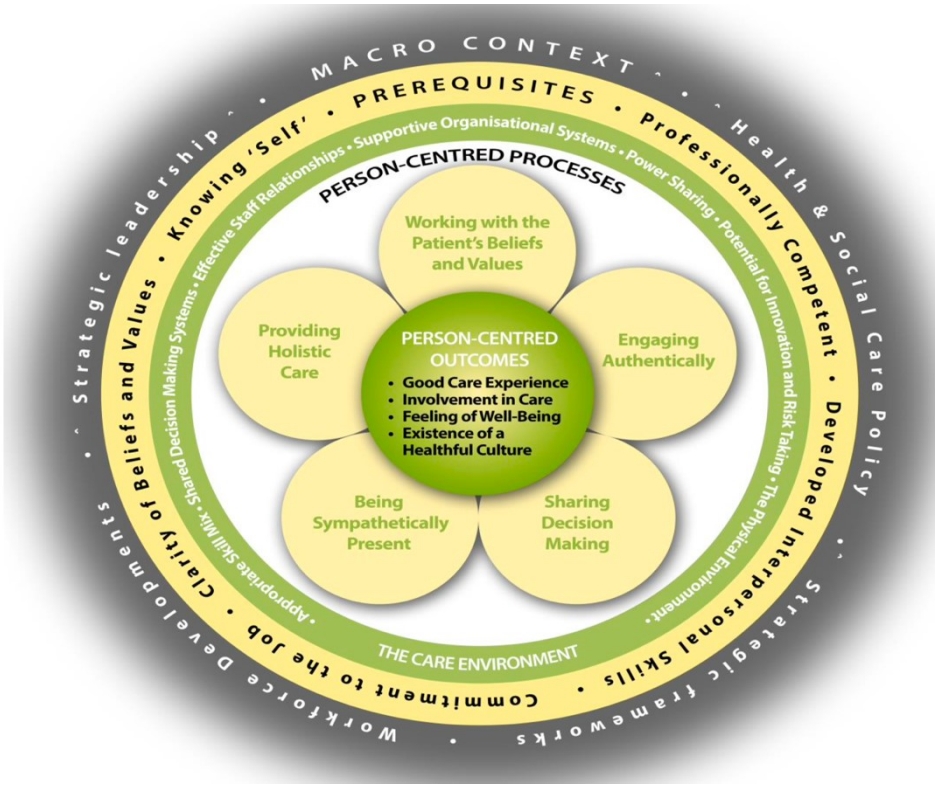
3. Place. The need to evaluate and adapt the environment to deliver person-centred care, not only the physical environment but systems such as decision making, staff relationships, organisational systems, power differentials and the potential of the organisation to foster innovation.
4. Self. Respect for values is integral to person-centred care.

McCormack (2004) notes the complexity of person-centred care and the need for nurses to shift beyond technical competence to authentic humanistic nursing practices. Understanding and enacting values is integral to person-centred care, but the pressures of everyday nursing may not allow this approach to prevail. McCormack and McCance (2006) further developed the four components of person-centred care to form their initial person-centred nursing framework which again comprises four elements:

1. *Prerequisites* of the nurse: professional competence, commitment to practice and clarity of beliefs and values.
2. *The care environment*: skill mix, effective staff relationships, shared decision making and supportive organisational structures and work systems.
3. *Person-centred processes.*
4. *Outcomes* of person-centred nursing.

McCormack and McCance's (2017) framework for person-centred practice has continued to evolve since its inception in 2006, review in 2012 and most recent iteration in 2017 (figure 2.14).

Figure 2.14 Person-centred Practice Framework



Source: Taken from McCormack and McCance (2017, p.42)

The framework's use and review in practice development programme settings has illustrated that it is not just relevant to nursing but to all health and social care professions and is indeed multi-professional. It concerns the whole system of care and highlights factors that affect person-centred care including, but not limited to, the person's experience of care giving, involvement in their care and the environment of care.

McCormack and McCance (2017, p.3) now describe person-centredness in healthcare as:

> an approach to practice established through the formation and fostering of healthful relationships between all care providers, service users and others

> significant to them in their lives. It is underpinned by values of respect for persons (personhood), individual right to self-determination, mutual respect and understanding. It is enabled by cultures of empowerment that foster continuous approaches to practice development.

Hardiman and Dewing (2019) discuss the relationship between person-centredness, person-centred care and person-centred cultures, outlining that person-centredness is about embedded practices within a specific type of culture that enable and facilitate the delivery of person-centred care. McCormack and McCance (2017) clarify that person-centred cultures are necessary for the delivery of person-centred care. McCormack and McCance (2006; 2010; 2017) suggest that person-centred care is about every person involved in the patient's care, not just the patient. From a staff perspective, it includes skill mix, effective relationships and shared decision-making. McCormack and McCance (2010) are clear that the use of the term 'person' in their work encompasses all involved in what they designate 'caring interactions', and therefore is inclusive not just of patients, their family and carers, but every member of the multidisciplinary healthcare team. McCormack et al. (2015) suggest that to be person-centred, there is a necessity for 'healthful' relationships between health professionals, their patients or clients and significant others.

2.5.3 Person-centred Care in Healthcare

McCance et al. (2011) suggest that the focus on person-centredness in healthcare reflects society's need to address ongoing issues of service delivery imbalance, and the requirement to move from a medical ethos to a more holistic and collaborative one. Ekman et al. (2011), a collaborative interdisciplinary group of professionals from health, design and business, supported by grants from the Swedish government, established the University of Gothenburg Centre for Person-Centered Care (GPCC) to study person-centred care in long-term illness. Ekman et al. (2011) acknowledge that person-centred care has demonstrated that collaboration between healthcare professionals and patients in relation to their treatment has improved both patient outcomes and patients experience of their care. For example, work in a regional aged care service in New South Wales, Australia involved nurses in the design and content

of a programme to enable them to feel empowered in leading their teams, with demonstrable impacts on workplace culture (Marriot-Statham et al., 2018). McCormack et *a*l (2010) discuss an evaluation undertaken as part of a national programme of practice development in residential care settings for older people in Ireland that aimed to place the development of person-centred cultures at the centre of practice development work. The findings illustrate the emphasis that person-centred approaches place on staff experiences of participating in care giving and the importance of effective teamwork, time and workload management, and relationships among staff in enabling the creation of a democratic and inclusive culture that in turn opens up spaces for the creation of person-centred relationships. Li and Porock (2014), in a review of nine studies of person-centred care of people with dementia in long-term care settings, found a significant reduction in psychotropic drug use and behavioural symptoms. Person-centred approaches lead to more involvement by people in their own care and associated improved outcomes (such as reduced blood pressure), and to increased satisfaction among healthcare staff with the quality of the care they deliver (Mead and Bower, 2002; McMillan et al., 2013).

McCormack et al. (2015) suggest that person-centred care practice is now well established not just in nursing but also in healthcare generally. However, the authors recognise that there is variation internationally in the approach to person-centred care implementation and innovation (McCormack et al., 2015). Buetow (2016) suggests that the further development of a person-centred healthcare system is dependent on writers and practitioners agreeing on a definition of 'personhood' that emphasises the distinction between the concept of personhood and the concept of 'patienthood'. Buetow (2016) further suggests that lack of agreement on a definition of what constitutes person-centred care leads to practitioners being unable to differentiate between person-centred care and patient-centred healthcare. Guastello and Jay (2019) suggest that the lack of consensus on the most critical elements of person-centred care has limited the ability to evaluate the impact of the implementation of person-centred care approaches. Dewing (2015) and, more recently, Dewing and McCormack (2017) have developed a model for identifying person-centred patterns, moments and culture which is elaborated on later when locating Lean Six Sigma in person-centred cultures.

According to McCormack et al. (2011), the healthcare literature utilises a great variety of terminology to reflect the concept of person-centredness, including terms such as 'personhood, person-centred, patient-centred, people-centred, client-centred, woman-centred, and relationship-centred care' (McCormack et al., 2011 p 3). Le Plege et al. (2007) and Slater (2006) (cited in McCance et al., 2011), the American National Quality Forum (2014) and Tannenbaum (2015) also highlight the profusion of terminology to describe person-centredness. This variation in the terminology may be problematic in the long term for a number of reasons:

- Person-centred care can be seen to mean all things to all people.
- Person-centred care may become meaningless rhetoric.
- Person-centred care may be paid lip service.
- The terminology may mean that the concept and practice of person-centred care may not be amenable to research.

Indeed, Dewing and McCormack (2017) challenge nursing to clarify how person-centredness is being defined. McCance et al. (2011) in their exploration of person-centredness identified related terms used in the literature that include patient-centred care (Drach-Zahvy, 2009), family-centred care (Shields, Pratt & Hunter, 2006), woman-centred care (Leap, 2009) and relationship-centred care (Nolan et al., 2004). Tanenbaum et al. (2015) feel that the actual meaning of patient-centred care can be contested and is not easily understood. Buetow et al., (2016), although specifically referring to caring for patients with Parkinson's disease, developed a table to illustrate what they understood the to be the differences between patient-centred care and person-centred care (figure 2.15).

Figure 2.15 Comparison of patient centred and person-centred care

Attribute	*Patient-centered care*	*Person-centered care*
Focus	Patient welfare	Respect for persons; reciprocated care
Personhood	Implicit	Explicit
Goal	Health maximization	Living as good a life as possible
Philosophy	Acting in socially defined, functional categories (e.g., patient) that carry rights, duties, and expectations (role theory)	Respect for the centrality and absolute value of persons as relational beings (personalism)
Ethics	Professional duty	Moral values and virtues of persons
Principles	Patients come first (primacy of patient welfare)	Persons come first
		Moral equality; equal moral interests are considered equally
	Respect for patient autonomy, especially patient agency	Authenticity, mutual agency, and bridging of competing moral interests
Care	Clinicians manage how they display their feelings (emotional labor)	Joyful and authentic care
Science	Historically quiet on science	Humanizes scientific practice

Source: Taken from Buetow et al. (2016, p.3)

Buetow et al. (2016) suggest that the research on the effectiveness of patient-centred care is in its infancy and that a Cochrane systematic review (Dwamena et al., 2012) found that a patient-centred care approach had mixed effects on patient health, behaviour and satisfaction. Buetow (2016) feels it is important to distinguish between person and patient-centred approaches as to treat patients as 'persons' does not account for the fact that not all persons involved in care are patients. McCormack (2017) warns of the danger of patient centredness disguised as person centredness. Person-centred care respects not only the patient but includes clinicians and other participants in care.

Ekman et al. (2011) suggest that person-centred care is different to patient-centred care, in its move away from a model of the patient as a 'passive target' of interventions to a model where the patient takes an active role in their own care. According to McCance et al. (2011), person-centeredness is a standard of care that ensures the patient is at the centre of care delivery. Dewing et al. (2015) suggest that to be truly person-centred in healthcare we must listen to what both the person receiving care and our colleagues are saying and must also take account of the others involved in the journey, such as family, friends and other healthcare staff. Recent work from Wareing-

Jones (2016) (cited in Dewing & McCormack, 2016) suggests that, while healthcare practitioners may have an appreciation of the concept of person-centredness, there is a tendency for them not to utilise theoretical models, and, more worryingly, they may be trying to practice person-centredness in an environment and culture that is not conducive to it. Dewing and McCormack (2016) note that attention to the specific types of culture that promote or prevent person centredness is missing in most definitions of person-centredness and stress that the cultural dimension needs to be addressed in every organisation.

Parlour et al. (2014) undertook a study to see if there was a relationship between person-centred care and a positive patient experience. A purposive patient sample (n= 600) was recruited from ten acute hospitals. All hospitals were involved in a larger study and areas represented varied from medical to maternity to give a broad range of interviewees. Results from the study, using approved instruments with acceptable psychometric properties, illustrated there is a relationship between a person-centred care approach and a positive patient experience.

Dewing and McCormack (2016) suggest that, regardless of definition, person-centredness speaks to a specific culture that is inclusive of, and applies to, everyone in the organisation and does not isolate but incorporates care. Lean Six Sigma, despite Lean's roots in the concepts of Kaizen, is a methodology that has often been applied in a technical manner that does not always attend to the cultural dimension. This leads to discussion of Lean Six Sigma in relation to person-centred care and person-centred cultures.

2.5.4 Person-centred Care and Lean Six Sigma

According to Kinsman et al. (2014), based on experience of Lean deployment in Saskatchewan, Lean should create a continuous cycle of learning that is led by and driven by the 'experts' in healthcare processes, patients, families, care providers and staff. This would appear to be an approach to process improvement that is synergistic with person-centred care and person-centred cultures. However, referring back to the literature search strategy (figures 2.1, 2.2), 22 publications were found which mention

person-centred care when discussing Lean Six Sigma use in healthcare, six of which specifically discuss Lean in the context of person-centred care, with one of these articles, from a nursing journal (Kelly 2013), cited repeatedly as one of the only analyses of Lean Sigma and person-centred care. The short article by Kelly (2013) contends that Lean methodology does not support person-centred care as its quest for standardisation is about the organisation's need to produce efficiencies. However, this is a broad statement in a limited and short overview of Lean and person-centred care and, to date, there is no empirical evidence to prove or disprove this point.

Williams (2017) reported on a clinical case study that utilised a combination of Agile (a supply chain improvement methodology with similarities to Lean), Lean, co-production and person-centred approaches to redesign an existing Chronic Obstructive Pulmonary Disease (COPD) pathway for patients. Williams notes that there is limited research on the use of Agile in healthcare; however, the case study illustrates how Lean principles could be used in conjunction with person-centred approaches to improvement in a healthcare setting. Both Lean and Agile were seen to play a role in delivery of the COPD services across primary and secondary care, with Lean recommended in the initial stages of the pathway to deliver timely results and Agile to allow flexibility in the pathway where community-based patients and healthcare professionals accessed it, allowing for a more person-centred process. More recently, a review was undertaken (Bhattacharyya et al., 2018) of healthcare improvements using Lean Six Sigma combined with training in Human Centred Design (HCD) and/or co-design in the USA and Canada to achieve person-centred care. Three points to note from this paper are that this combination is still in its infancy, the authors offer no definition of their understanding of person-centred care, and person-centred care is seen as an 'outcome' rather than as a methodology to enable better experiences for patients and staff. At the study site graduates of the Lean Six Sigma education training programme are beginning to publish work they have undertaken using both Lean Six Sigma and person-centred approaches to improvement (Murphy et al., 2019; Connolly, Teeling & McNamara, 2020; Donegan et al, 2021), indicative of the contribution of Six Sigma, in addition to Lean, to person-centred care and cultures, illustrating that these methodologies can be used together.

McCormack (2017) notes that healthcare can rely exclusively on measurement (metrics), hard evidence and tangible outcomes, which are not facilitators of person centredness. McCormack et al. (2015) state that healthcare delivery needs to move towards a culture that contextualises and integrates the 'hard' evaluation of outcomes and programmes within an overarching person-oriented evaluation framework (McCormack, 2015).

2.5.5 Lean Six Sigma, Person-centred Care and Person-centred Cultures: Synergy and Divergence

Following on from the exploration of integrated approaches to improvement incorporating Lean Six Sigma and person-centred care, the review has enabled identification of some areas of synergy and divergence between them, which is elaborated on below.

Synergy 1: Respect for persons

Respecting the needs and preferences of the individual is key to person-centred care (Moore et al., 2016) and respect for persons is central to person-centredness (McCormack, 2003). The concept of respect in Kaizen led to Toyota adopting a philosophy with two pillars: continuous improvement and respect for people (Liker, 2004). Indeed, in Toyota they say that it is their respect for people that enables continuous improvement. This is important as it not only respects people but recognises them as 'moral peers' not merely operatives or drones for care delivery. As alluded to earlier, the philosophy of Kaizen may often be lost in the rush to continuous improvement and in Lean Six Sigma application in healthcare, a return to the Lean value of respect for not just people but persons can be an important integrator of person-centred care and Lean Six Sigma. Dewing et al. (2015) discuss the importance of knowing our own, our colleagues', our patients' and our organisations' values and beliefs. This is important because these values and beliefs underpin and inform our work and practice. Dewing et al. (2015) see the clarification of values and beliefs as essential to person-centred practice. Clarifying values and beliefs may, therefore, be

an important enabler of developing person-centred Lean Six Sigma practice in healthcare settings.

Synergy 2: The Voice of the Customer

Womack and Jones (2003) state that the initial step in Lean implementation in healthcare is to make the patient central to the process and to include time spent with the patient and patient comfort as key performance metrics, with an emphasis on patient involvement in their own care. The 'value stream' of Lean healthcare (Womack et al., 2005; Burgess & Radnor, 2013) is the patient journey which is reflected in the idea of 'the whole patient experience' in patient-centred care (National Ageing Research Institute [NARI], 2007). Continuous improvement is a key component of Lean thinking (Womack et al., 2005) and continuous improvement along with innovation is a key part of person-centred care (Dewing et al., 2015).

A key Six Sigma tool for identifying the 'Voice of the Customer' is the Critical to Quality (CTQ) tree. This is a tool which is used to:

1. Identify the **needs** of the customer (e.g. patients, staff, family).
2. Identify what **drivers** the organisation should have in place to meet these needs.
3. Identify the **metrics** to ensure that this driver is meeting the need.

The CTQ takes information collected from customers and translates it into critical and specific process requirements that are measurable (Riebling et al., 2018). Lean, Six Sigma and Lean Six Sigma all seek to define what exactly is valuable in a healthcare setting from the perspective of the customer (the patient) or end user (Radnor et al., 2012; Found & Harrison, 2012; Williams, 2015, 2017; Teeling et al; 2019). The terminology 'Voice of the Customer' (VoC) is used in Six Sigma to denote the expectations of the customer (Found & Harrison, 2012). Valuing the person as an expert in their life experience and respecting this by considering the whole person (NARI, 2007) is kept to the fore in both Lean and Six Sigma by listening to the 'voice of the customer' (Pande et al., 2002). Womack and Jones (2003) suggest that

understanding what the customer values is the first Lean principle; however, Found and Harrison (2012) found little in the literature to define what customer value was.

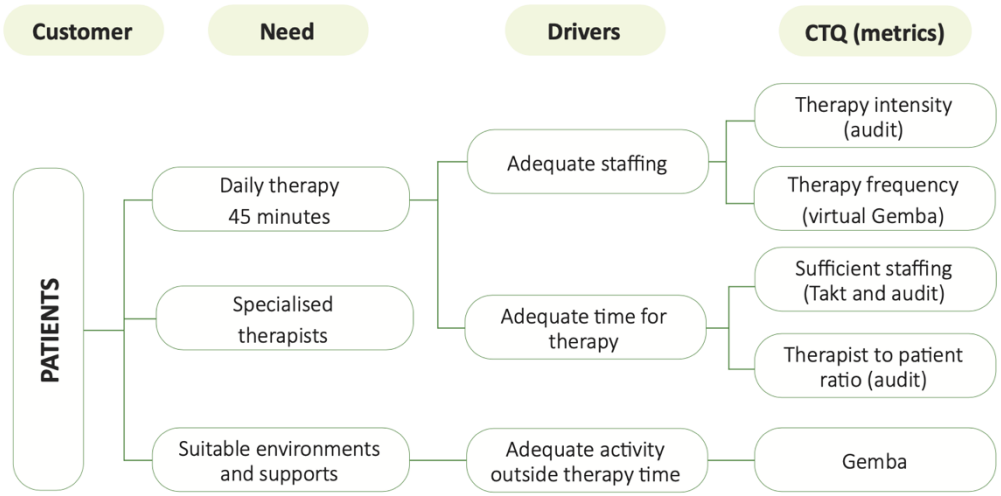
Waring and Bishop (2010) suggest that any reorganisation of healthcare work using improvement methodologies such as Lean should take account of the interactions among, and the mediating effects of, different actors and social structures over time. The University Lean Six Sigma education and training programmes (the intervention) utilise the 'voice of the customer' approach; however, expand the definition of the 'customer' to include anyone who 'touches' the process, not just the patient and their family. For example, in a Lean Six Sigma project on stroke patient nutrition (Teeling et al., 2019), eighteen people were involved in the process of ensuring the patient had a nutritious, hot meal, and for each of these, their 'voice' was sought. Using this approach, Lean Six Sigma standardised care pathways, whilst focusing on the patient as the primary customer; however, in listening to all voices the project can perhaps be said to exemplify a person-centred approach. Such an approach can ensure that Lean Six Sigma programmes in healthcare do not forget the other people involved in delivering care, thus aligning more to a person-centred as distinct from a patient-centred care model of delivery. According to Veech (2004), in a conventional organisation, the approach is to get something from the employee (such as more productivity) rather than giving something to the employee (such as opportunities). Lean Six Sigma initiatives enable employees to work in an environment that both motivates and sustains (Veech, 2004) and determining whether adopting a person-centred approach strengthens this in a synergistic way is relevant to this research.

Kelly (2013) suggests that the uniqueness of each workforce, organisation and its inherent culture, factors critical to a person-centred care approach, are not considered in Lean Six Sigma. Similarly, Curatolo et al. (2014) argue that person-centred care promotes individualised care as opposed to Lean's standardisation of care delivery, with Lean failing to explore the interactions among people, human behaviour and the work environment. However, this may not be true in all contexts. Williams (2015) discerned some similarities between the approaches to patients that exist in Lean and person-centred care, including understanding value from the voice of the consumer,

seeing the patient experience as integral, continual improvement in system performance, the pursuit of perfection and pulling resources to the patient or pulling the patient to the next step. However, this points to the importance of how Lean Six Sigma is used in practice, not just 'what it is'. This again points to the possibility of an integrative approach to Lean Six Sigma deployment within an overarching framework of person-centred cultures.

Rath and Strong (2002) and George et al. (2005) discuss how the 'Voice of the Customer' is gathered and then mapped onto a Six Sigma tool known as a Critical to Quality (CTQ) template. The CTQ tool is designed to capture the key measurable characteristics of a process or service whose performance standards must be met in order to satisfy the customer (Rath & Strong, 2002). Rath and Strong (2002) and George et al. (2005) advocate that the only way to capture the customer voice is to talk to them, through methods including interviews, focus groups, observational studies and surveys. Using any of the above, alone or in combination, the gathered information is mapped onto the CTQ template to map the customer voice. These methods of gathering requirements from customers are in keeping with person-centred approaches to improving care practices, which utilise observations, narratives, conversations, focus groups and workshops (Dewing et al., 2015). An example of a healthcare CTQ measuring the needs of patients who were recovering from stroke is provided in figure 2.16.

Figure 2.16 CTQ



Source: Connolly, Teeling & McNamara (2020, p 7).

In relation to the CTQ, contexts and circumstances change (e.g. staff leave or move, patients or family members die), so CTQs must constantly be critically examined and refined as necessary (Goh, 2002). Whilst it can be argued that Lean Six Sigma application in healthcare does put the patient first in attending to respect for persons and the 'Voice of the Customer', the application of the methodology can focus on the 'patient' voice rather than the 'person' voice with limited inclusion or participation of other 'customers' (e.g., relatives or staff). According to McCance et al (2013), healthcare staff can find the environment in which they have to practice:

> ...,challenging, often stressful, sometimes chaotic and largely unpredictable, it is important to ask how we can ensure person-centredness becomes an everyday cultural norm.
> (McCance et al 2013, p.11)

In this regard, the 'Voice of the Customer' applies to staff (Kaltenbrunner et al., 2019) as well as patients and their families and in the case of the example outlined in figure 2.16 a separate 'Voice of the Customer' and CTQ was carried out for the staff involved in patient therapy. This ties into the person-centred care philosophy of Collaborative, Inclusive and Participatory (CIPs) approaches (McCormack et al., 2017).

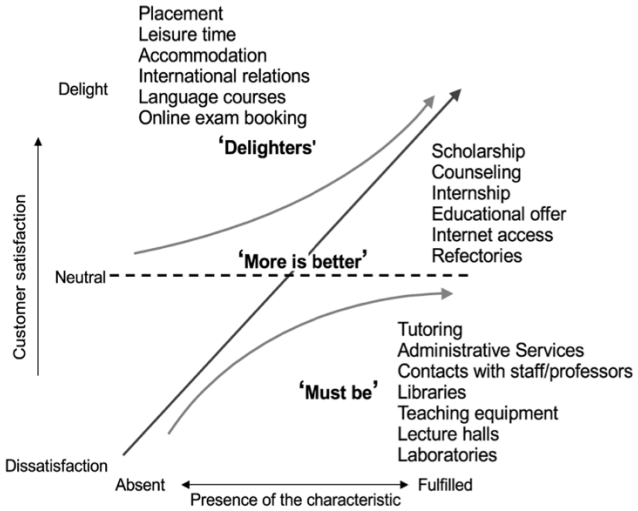
Synergy 3: Staff empowerment

A person-centred culture empowers staff to engage in ongoing development and quality enhancement (Dewing & McCormack, 2017). Lean Six Sigma has a similar approach to empowering both staff and patients, using the concept of the Kano model. The Kano model was developed by Professor Noritaki Kano in the 1980s. Kano had a background in quality management and engineering. The model is based on the theory of product development, and customer satisfaction and quality, which classifies customer preferences into five categories (Shahin & Nekuie, 2011):

1. Must be or have (expected needs): can dissatisfy if missing but does not increase satisfaction.
2. One dimensional (normal needs/satisfiers): the more these are met, the higher the satisfaction level of the customer.
3. Delighter (latent needs): absence does not cause dissatisfaction but will delight customer if present.
4. Indifferent: the customer is indifferent to the presence or absence of this feature
5. Frustrator: a feature thought to increase satisfaction that does the opposite.

An example of the Kano model (figure 2.17) illustrates its use in outlining insights for a university on the expectations and motivations of potential students decision making process when choosing which university to attend.

Figure 2.17 Kano model of University services



Note: The order in which the services appear reflects graduation through the vertical axis

Source: Taken from Petruzzellis et al. (2006, p. 360).

Although the example in figure 2.17 is not related to patients, it is related to healthcare students, and illustrates that the Kano model can be used to engage fully with all healthcare professionals and those involved in receiving and giving care. This is an example of how elements of Lean Six Sigma lend to person-centred care practices and can feed into person-centred cultures. This shifts the discussion away from the view of Lean Six Sigma as purely about the process. However, another key synergy of Lean Six Sigma and person-centred care is in the actual observation of process, which is now discussed.

Synergy 4: Use of Observational Studies

In working in developing practice in a person-centred way, observations are often used to study the workplace (not the patients or staff) (Dewing et al., 2015). These observations are then fed back to and discussed with staff to inform a practice development plan. Section 2.3.4 already alluded to the Lean approach to observational studies, known as Gemba. Womack (2013) describes Gemba as paying a visit to the

'real place' or where the process or work takes place. The Japanese developed the concept of Gemba walks (Ohno & Bodek, 1988) to enable staff to stand back from the work and the process and to just observe. The mantra, 'if you can observe you can measure, if you can measure, you can improve' applies to Gemba walks.

Importantly, a Gemba walk is not an opportunity for critique or fault finding of staff. It is also not a walk around which seeks to enforce policy adherence. It is in no way punitive. Linking back to the essence of the concept of Kaizen, a Gemba walk is always approached from a place of mutual respect and of making thinking better. The processes involved in both approaches to observations are virtually identical and, therefore, this is an important synergy between Lean Six Sigma and person-centred care.

Influencing Synergy and Divergence: Quality

The terms 'quality' and 'quality improvement' can mean different things to different people depending on the contexts and circumstances in which they find themselves (Health Foundation, 2016). Within healthcare, there is no universally accepted definition of quality, however it has been identified as having six dimensions: that healthcare must be safe, effective, patient-centred, timely, efficient and equitable (Institute of Medicine, 1990). In Ireland, the Health Service Executive's focus is on providing a healthcare service that is person-centred, effective, safe and actively promotes better health and wellbeing (Health Service Executive, 2016).

However, this does not necessarily imply that quality and process improvement methodologies are in and of themselves person-centred. Whilst McCormack and Watson (2017) acknowledge that there is much to applaud in quality improvement initiatives such as the use of the PDSA (Plan, Do, Study, Act) cycle in the Model for Improvement, they question whether they actually achieve culture change. Continuous improvement is a key component of Lean and Six Sigma thinking (Womack et al., 2005, Snee, 2010), and continuous improvement along with innovation are key components in developing person-centred care and cultures (Dewing et al., 2015).

Thus, there appears to be a synergy. However, within the review a point of divergence was also found for discussion.

Lean Six Sigma has a number of methods and tools for identifying the Voice of the Customer such as the Critical to Quality tree (CTQ) discussed above that captures the key measurable characteristics of a process or service whose performance standards must be met in order to satisfy the customer (Rath & Strong, 2002). Methods to understand customer and stakeholder experiences are also found in programmes aimed at enhancing person-centred cultures and care (Dewing et al., 2015). However, based on the literature review, there exist theoretical and methodological divergences on core principles and practices such as how the customer voice is accessed, attended to, interpreted and acted upon, the focus on outcomes as distinct from experiences, and the relative emphasis on metrics and measurement for improvement. Therefore quality could be seen as currently influencing both improvement methodologies. Most importantly, in some contexts there can be a dichotomy between the traditional process improvement view of creating value for the customer (Williams, 2015) and the concept of values as a way of life (McCormack et al., 2017). The principal aim is to deliver quality care in a way that respects both patients and staff, as advocated by McCormack and Watson (2017).

Having discussed the key synergies between Lean Six Sigma and person-centred care and considered how quality influences and straddles both methodologies, there now follows a discussion of the divergences between them.

Divergence 1: Core Values

Williams (2015) notes that value is seen in a wider context in person-centred care with a focus on patients, families and staff and social values, whereas Lean focuses on improving processes. This suggest that wider social values could be excluded if process improvement does not occur incrementally and with the inclusion of key stakeholders. However, as discussed, respect is linked to value and Lean Six Sigma does not necessarily negate the inclusion of social values in its scope of practice. Again, this speaks to ‘how’ we use Lean Six Sigma, which can be adapted to be

consistent with person-centred cultures. Indeed, Williams (2015) argues that in relation to Lean, if it were implemented focusing only on efficiencies, it would be at odds with its own underlying principles and those of quality improvement, and with the idea of creating value for the customer, highlighting that value is a key element of both Lean and person-centred care. Understanding the difference between value to the customer and the concept of values as a way of life (McCormack et al., 2017) is important in developing this synergy of value. Seeking the patient's perspective and adding the voice of family and carers can add strength to the development of processes and procedures that are built with the patient at the centre. Therefore, there is potential for Lean Six Sigma projects to build systems that are based on patients' and practitioners' values, develop environments where the flow of patients, materials and information is seamless, and in which a culture of continuous improvement is integrated into the system, and the patient and family are seen as a fundamental part of the process.

Divergence 2: Standardisation

Langabeer et al (2009) argue that by standardising processes we limit healthcare professionals' decision making and autonomy and thereby hinder their ability to provide safe and effective care. Morgan and Yoder (2012) suggest that person-centred care incorporates four characteristics; they are holistic, individualised, respectful and empowering. The standardisation that comes from Lean Six Sigma initiatives can be difficult to tailor to individual patients, rather than groups, and projects specific to individual patients rather than groups of patients have yet to be looked at. However, it has already been addressed how standardised processes can lead to positive patient outcomes and increased staff satisfaction (section 2.4). In healthcare, there are instances where diversity in care approaches enables staff to meet the needs of individual patients (Saurin et al 2013) and Lean Six Sigma must make allowances for that.

Divergence 3: First Principles

Black (2009) claims that Lean does not fully consider the complexity of social interactions within healthcare settings. Further research on sociotechnical dynamics

and Lean is required to minimise the risk of failure or future resistance by key players (Joosten et al., 2009); for example, reviewing the interaction between human behaviour and technology. Such research has already taken place in the airline industry where the concept of distributed cognition recognises how information resides in and flows among humans and computers. Lean has, as a first principle, the concept of understanding value (Williams, 2015). Person-centred care has as a prerequisite the assessment of professional competence, commitment to practice and clarity of beliefs and values (William, 2015). According to McCormack (2014), an organisation that is person-centred has the following attributes:

- A caring approach to how we meet needs
- Nurtures effective relationships
- Promotes social belonging
- Creates meaningful spaces and places
- Promotes human flourishing

Understanding the beliefs and values of staff leading Lean Six Sigma initiatives, and not just those of the patients and staff they are working with, could potentially help to take account of the complexity of social interactions and empower Lean Six Sigma practitioners and students. Once again this speaks to the potential of an integrated approach to Lean Six Sigma and person-centred care.

2.5.6 Revisiting the philosophical roots of Lean Six Sigma and Person-centred care and cultures

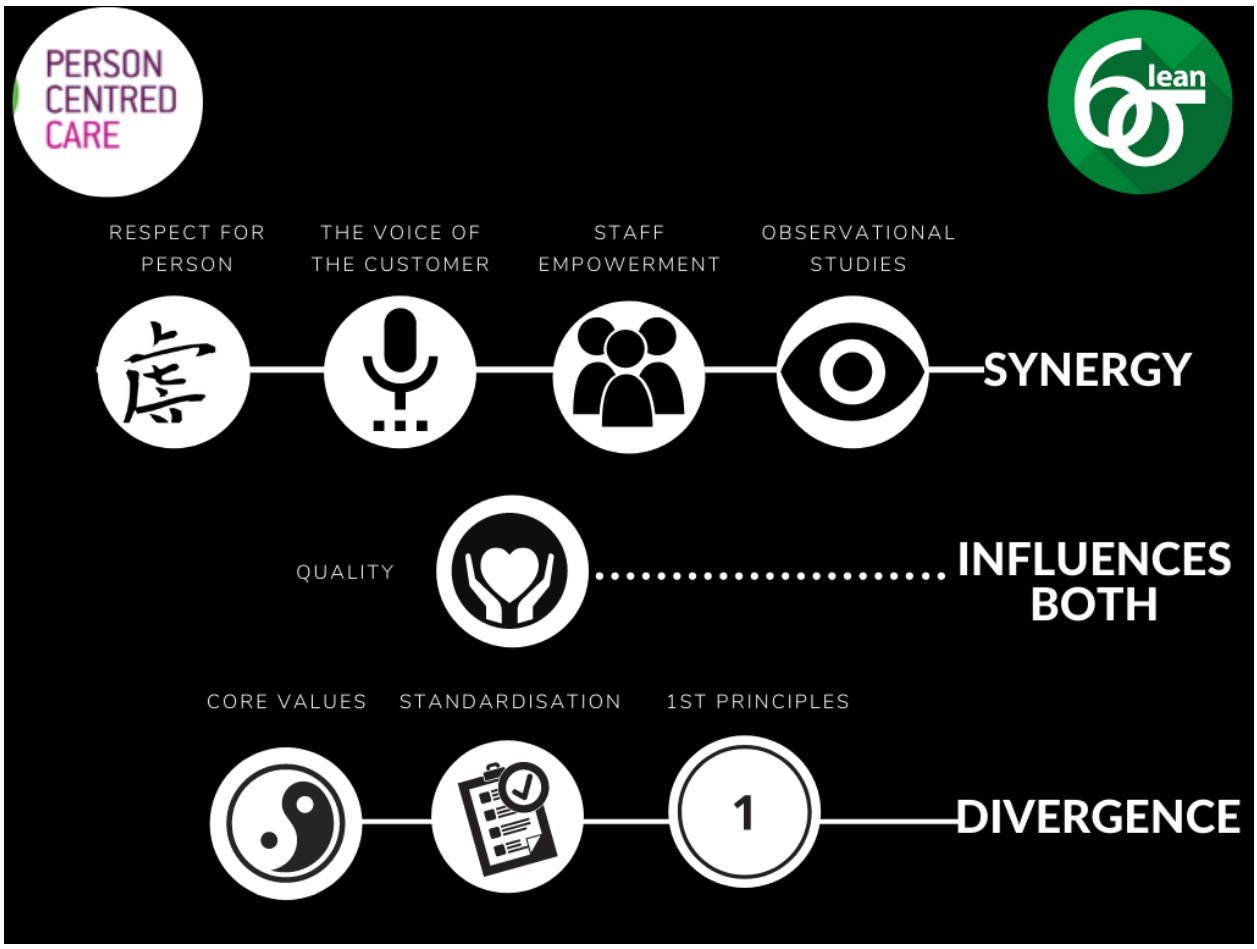
The literature has been used to distil key synergies and divergences between both Lean Six Sigma and person-centred care and cultures (section 2.5.5) that are summarised in Figure 2.18. The identification of this synergy and divergence between both methodologies leads to further discussion of their philosophical roots. Dewing, McCormack and McCance (2021) suggest that the foundation of person-centredness is shaped by a philosophical understanding of what a human person is and what we believe and value personhood to be. As previously discussed, personhood is respect for persons (McCormack & McCance, 2017) which is synergistic with Lean's original

philosophical underpinning of respect (Liker, 2004). Person-centred practice has as a starting point a philosophical exploration of what a person is as viewed through their view of the world (Dewing, McCormack & McCance, 2021). It is evident from the review that although the 'person' elements of Lean Six Sigma are often overlooked in the literature, that they were clearly present in the development and dissemination of its early methodological development and work, particularly so in the case of Lean . As previously discussed, the Lean concept of Kaizen speaks to a wider application of the principle of respect for people, and is inclusive of personal, home, social and working life (Imai, 1986) contributing to an understanding of Lean as a philosophy of life (Imai, 1986; Wittenberg, 1994; Gondhalekar et al., 1995; Bateman, 2002; Olexa, 2002a,b; Liker, 2004; Teeling, Dewing & Baldie, 2020). The drift from the original philosophical intentions of Lean of starting with peoples' values and respect for people, or 'fidelity' to these intentions may in part be due to the fact that in healthcare Lean Six Sigma is predominantly used for specific process improvement rather than implementation as an organisational philosophy (Moore, 2001; Lawal et al., 2014; Flynn et al., 2018). This is compounded by a tendency for improvement practitioners to view Lean Six Sigma solely at the operational level of a quality improvement tool for continuous improvement, with a failure to focus on Lean as a management philosophy, underpinned by principles and values (Suárez Barraza et al., 2011).

In section 2.3.2, the principles of Lean and Lean's original eight steps (Marksberry et al., 2011; Simon & Houle, 2017) were discussed. Recent work by Wackerbarth et. al (2021) speaks to the concept of 'fidelity' to these steps. A review of the literature on Lean use in healthcare (n=605), found, that at an operational level, healthcare practitioners' Lean projects completed only 2.77 of the eight steps (Wackerbarth et. al.,2021). This links to earlier discussion on Lean implementation, and the work of Radnor et al. (2012) that similarly found Lean implementation tended to involve its use through a small range of specific tools or techniques, and that there was wide variation in Lean application in the NHS (Burgess & Radnor, 2013). Wackerbarth et al. (2021) acknowledge that this 'infidelity' to both Lean principles and steps may be due to organisational tactical decisions and limited resources, however, they also claim that this may be due to a lack of understanding of Lean as a philosophy. Radnor et

al.(2012) suggest that health service leaders have a tendency to view Lean as a collection of operational tools, rather than understanding it as a broader system-wide improvement philosophy. As evidenced within this review, this lack of understanding of Lean Six Sigma at a philosophical level is missing in much of the literature (Burke, 2008; Stone, 2012; Teeling, Dewing & Baldie, 2020; Wackerbarth et. al.,2021).

Figure 2.18 Synergies and Divergences between Lean Six Sigma and Person-centred Care and Cultures



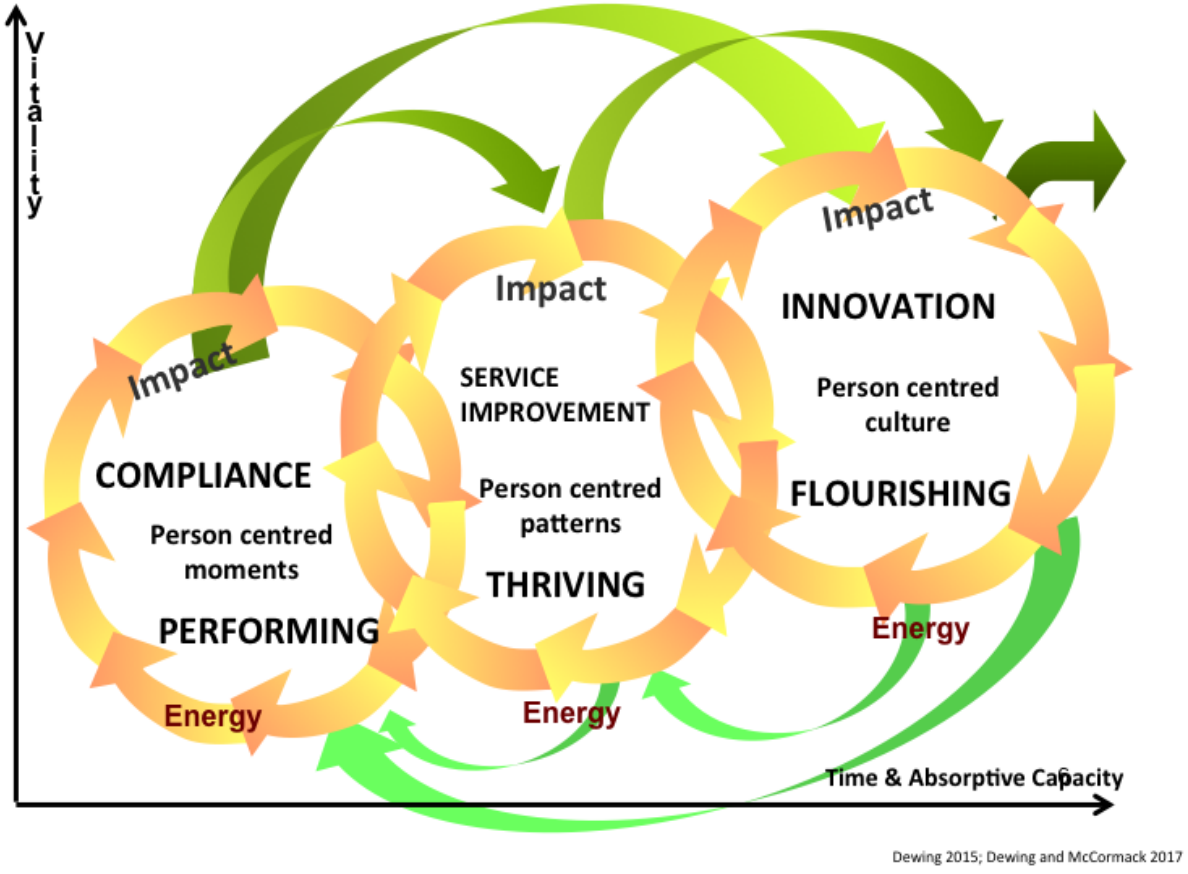
Source: Taken from Teeling, Dewing and Baldie (2020, p.19)

2.5.7 Summary

This section has discussed person-centred care and person-centred cultures and their interaction with Lean Six Sigma in a healthcare setting. The literature has been used to distil key synergies and divergences between both Lean Six Sigma and person-

centred care and cultures. This review indicates that the synergies could be strengthened to develop an integrative approach to Lean Six Sigma and person-centred care and that the divergences could be minimised on to bridge the gap and more closely align Lean Six Sigma with person-centred cultures. Williams (2015) has developed a useful conceptual model that could inform practitioners using Lean to deliver person-centred care and highlights the need for further research to test its application in practice. Dewing (2015) and Dewing and McCormack (2017) locate service improvements (such as Lean Six Sigma initiatives) in relation to person-centredness and person-centred cultures (Figure 2.19).

Figure 2.19: The Compliance Service Improvement and Innovation Model (CoSIITI)



Source: Taken from Dewing and McCormack (2017, p.155).

This model supports the findings on synergies and divergences, and shows that Lean Six Sigma (a service or process improvement) does contain person-centred patterns. It

also suggests that further work is required to strengthen synergies and reconcile areas of divergence to shift towards a person-centred culture. The current lack of empirical evidence supporting the integration of process improvement approaches such as Lean (Williams, 2015, 2017), Six Sigma, and Lean Six Sigma (Teeling, Dewing & Baldie, 2020) with person-centred care highlights the need for further exploration of the conceptual bases of these approaches. Some preliminary work towards integration includes adapting value stream design to incorporate individualised customisation (Naim and Gosling, 2011). Stirk and Sanderson (2012) advise that Lean, Six Sigma and Lean Six Sigma are valuable continuous improvement tools that are not out of place in a person-centred organisation, which has a continual focus on the people whom the organisation supports and on community contribution (Williams and Sanderson, 2003). Lean Six Sigma teams working on initiatives can only benefit from a person-centred approach, and working in person-centred teams can influence how long a worker stays in an organisation (Stirk & Sanderson, 2012).

Table 2.8 Key points of review relating to Person-centred care and cultures.

Key message	Articulated by
Person-centredness in healthcare speaks to the formation and fostering of healthful relationships between all care providers, service users and their significant others.	McCormack & McCance, 2010, 2015,2017.
Person-centredness is about embedded practices within a specific type of culture that enable and facilitate person-centred care.	McCormack & McCance, 2017; Hardiman & Dewing, 2019.
Person-centred care components can be applied by any healthcare professional. They encompass Relationships, Social World, Place and Self.	McCormack, 2004.
The Person-centred practice framework comprises four elements including prerequisites of the healthcare professional, the care environment, person-centred processes and outcomes of person-centred care.	McCormack & McCance, 2006, 2012, 2017.
Person-centred care has demonstrated that collaboration between healthcare professionals and patients in relation to their treatment has improved both patient outcomes and patients experience of their care	Mead and Bower, 2002; McCormack et al., 2010; Ekman et al., 2011 ; McMillan et al., 2013; Marriot- Statham et al., 2018).
There is variation internationally in the approach to and understanding of person-centred care and innovation.	McCance et al., 2011; Dewing, 2015; McCormack et al., 2015; Buetow, 2016; Dewing & McCormack, 2017.
There is little literature on the combined use of person-centred care and Lean Six Sigma.	Williams, 2017; Teeling, Dewing & Baldie, 2020.

Service improvement (using methodologies such as Lean Six Sigma) has been located in relation to person-centredness and person-centred cultures.	Dewing, 2015; Dewing &McCormack, 2017.
Although there is a lack of empirical evidence supporting the integration of process improvement approaches such as Lean, Six Sigma and Lean Six Sigma with person-centred care, Synergy and Divergence have been identified between them, an understanding of which could facilitate their combined use.	Williams, 2015, 2017; Connolly, Teeling & McNamara, 2020; Teeling, Dewing & Baldie, 2020.
There is more recent evidence of the combined use person-centred care and Lean Six Sigma.	Murphy et al., 2019; Connolly, Teeling & McNamara, 2020; Donegan et al., 2021.
The concept of Kaizen emphasises 'respect for person.	Imai, 1986; Elgar & Smith, 1994; Liker, 2004; Mazzocato et al., 2010, 2016.
There is drift from the original philosophical intentions of Lean of respect for people, or 'fidelity' to these intentions by Lean Six Sigma practitioners.	Radnor et al., 2012; Burgess & Radnor, 2013; Marksberry et al., 2011; Simon & Houle, 2017; Wackerbarth et. al., 2021.

There now follows discussion of the CMOcs developed from this review and examine them in relation to the conditions which need to be in place for the synergies between Lean Six Sigma and person-centred care to be optimised.

2.6 CMOcs Developed from the Realist Review

2.6.1 Introduction

Wilson et al. (2014) point out that everything we do takes place in a context and that any study that fails to consider context ignores human factors. This review of the literature has illustrated, however, that most research on the implementation of Lean, Six Sigma and Lean Six Sigma in healthcare has not addressed the contextual factors and mechanisms that influence the sustainability of their improvement efforts (Young & McLean, 2008; Dellifraine et al., 2010; Radnor & Osborne, 2013; Andersen et al., 2014). Holden et al (2014) state that, while case studies can provide insights into Lean implementation, they do not offer a study design that assesses contextual differences or examines their link to the outcomes of Lean initiatives. Holden et al. (2014) recommend a multiple case study approach, combined with Pawson and Tilley's (1997) Realist Evaluation methodology. Realist evaluation is my chosen methodology

(chapters three and four) and addresses the following question in relation to Lean Six Sigma in healthcare:

> how and why does this work and/or not work, for whom, to what extent, in what respects, in what circumstances and over what duration?
>
> (Westhorp 2014, p.4)

According to Holden et al. (2014), realist evaluation is useful for looking at interventions (such as Lean Six Sigma) reacting with context (e.g., staff with experience of process improvement) to trigger mechanisms (e.g., staff engaging in daily process improvement) that generate outcomes (e.g., staff satisfaction). However, Holden et al. (2014) acknowledge that this approach has been used in the study of Lean (Mazzacato et al; 2012) and Lean Six Sigma (Black, 2009) in only a small number of cases. Realist Evaluation was the methodology of choice for the evaluation of more recent Lean initiatives in Canada (Kinsman et al., 2014; Mackenzie & Hall, 2014; Flynn et al., 2019). Its ability to explore the outcomes of Lean Six Sigma in an exploratory way allows for the investigation of the range of impacts it has, including those related to person-centred care and person-centred cultures. It is, therefore, a suitable methodology for this research.

To look forward briefly to research design (set out in chapters three and four), Realist Evaluation is concerned with four core concepts (Tilley, 1998):

1. **C**ontext. What conditions are required for a measure to trigger mechanisms or to produce a particular outcome pattern?
2. **M**echanism. What is it about a measure that may lead to it having a particular outcome? How does the intervention work?
3. **O**utcome or outcome patterns. What are the practical effects in a given context?
4. **C**ontext, **M**echanism, **O**utcome **C**onfiguration (CMOc). What works for whom and in what circumstance

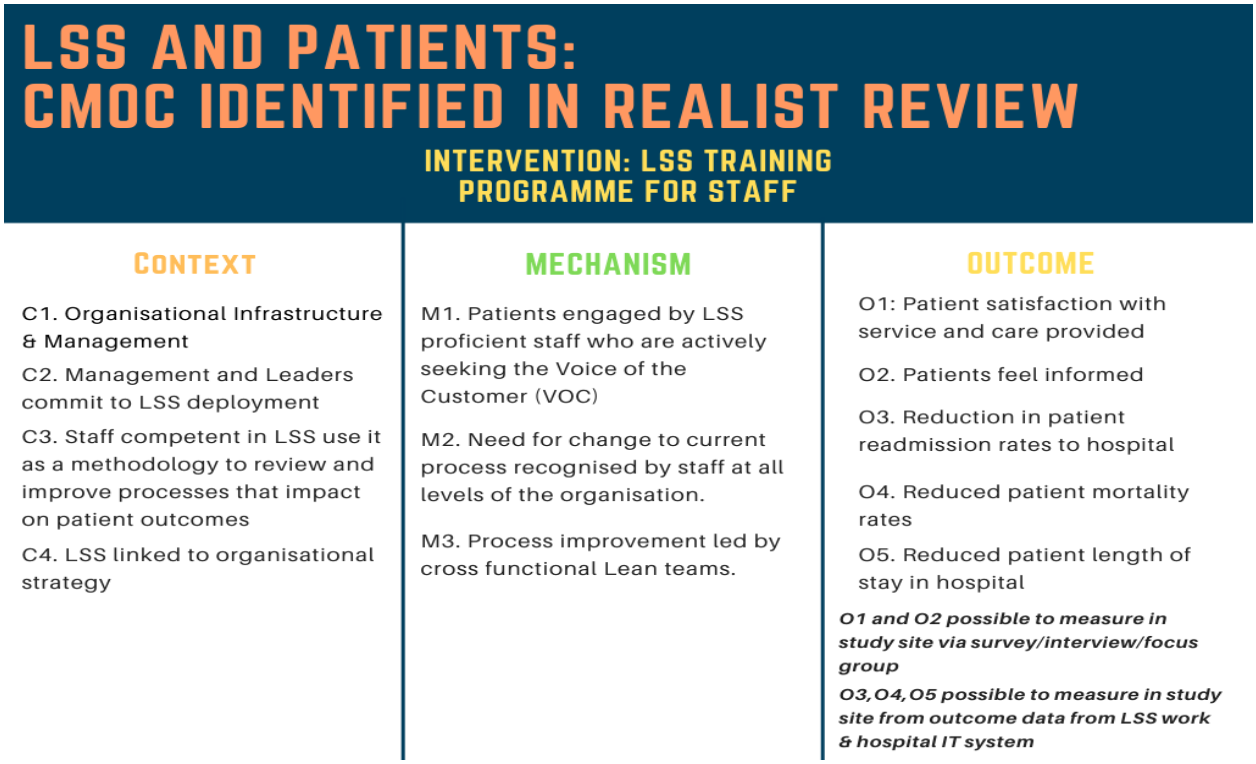
The methodology has facilitated development of three initial CMOc from the literature that enabled understanding of 'what works for whom in what circumstances' (Tilley,

2000) in relation to the contribution of Lean Six Sigma to person-centred care. Each of the three CMOcs developed from this realist review are now discussed.

2.6.2 CMOcs from the Realist Review

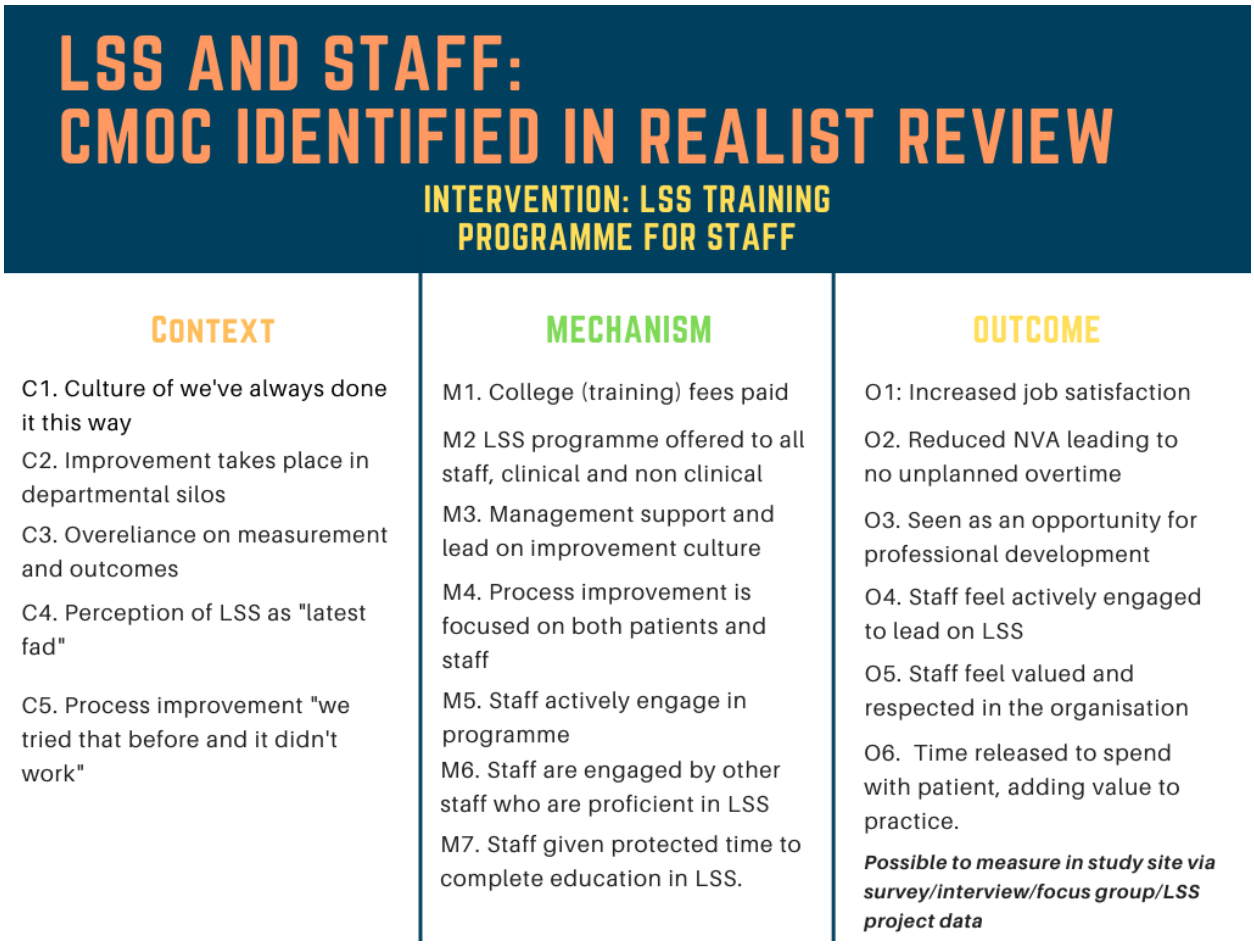
The Realist Evaluation model for evaluation allowed understanding of what aspects of an 'intervention' make it effective or ineffective and also to gain insight into the contextual factors which would be required to replicate it in another area. Understanding what aspects or combinations of specific Lean Six Sigma interventions contribute to person-centred cultures at the study site and identifying the relevant contextual factors, will enable any contribution to be enhanced and potentially replicated in other group hospitals. In relation to the study site, the intervention has been identified as the Lean Six Sigma healthcare education and training programme which commenced in 2014. Findings from the literature were synthesised to illustrate three CMOcs that were shown to be present when Lean Six Sigma was an intervention in a healthcare context, and that make explicit the contextual factors and mechanisms thought to mediate the impact of Lean Six Sigma on person-centred care and person-centred cultures. Each CMOc is presented in the order of patients, staff and organisational outcomes, following the format of the review above (sections 2.4.3; 2.4.4 and 2.4.5).

Figure 2.20 CMOc1: Lean Six Sigma and Patients



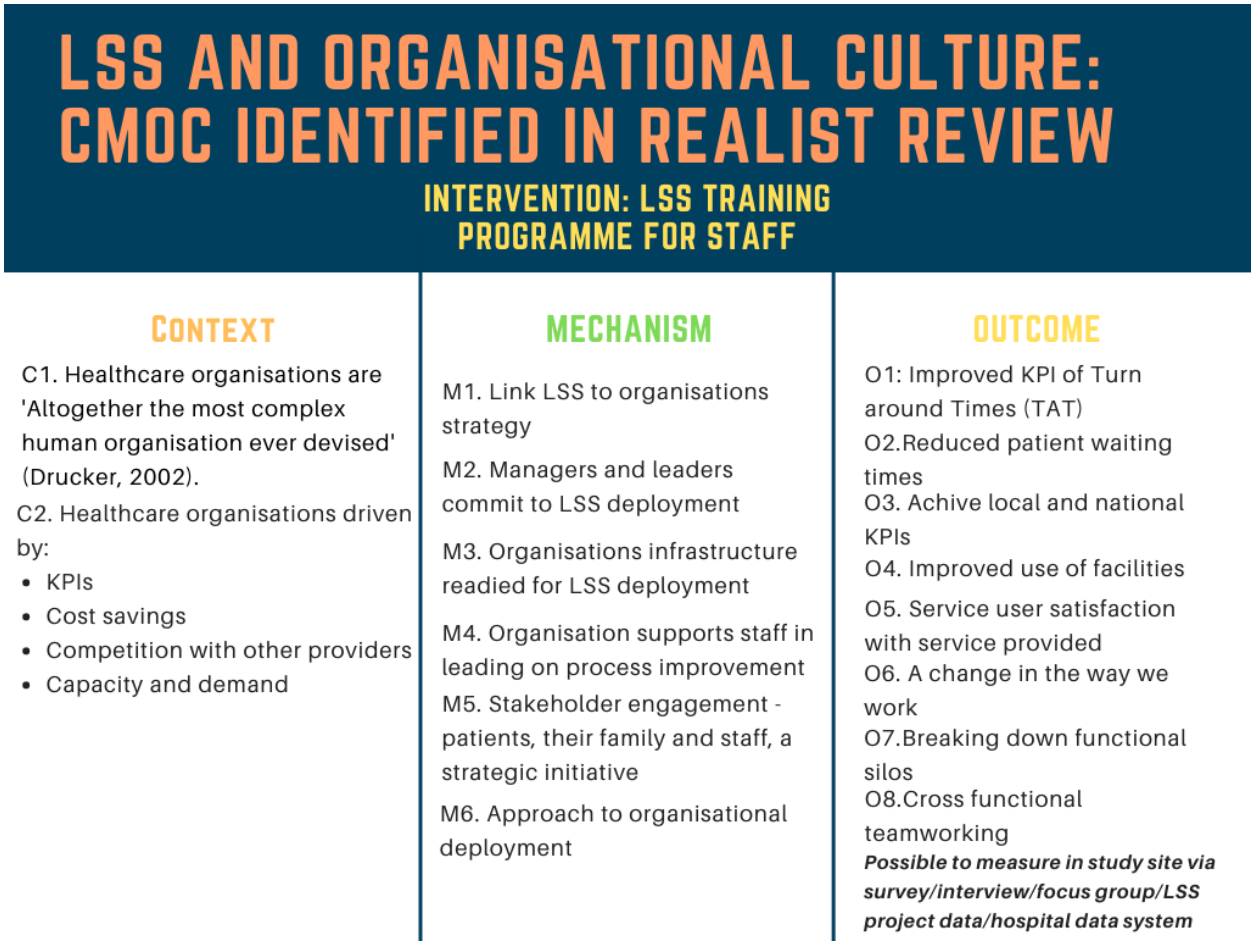
The patient CMOc illustrates the most commonly-occurring findings in the literature review. It hypothesis that these outcomes have been realised through the intervention of the Lean Six Sigma education and training programme at the study site will be tested in chapter four. The text in ***bold italics*** indicates which outcomes identified in the literature can be measured and tested at the study site as part of this research (chapter four). This suggests where and how divergences between Lean Six Sigma and person-centred care could be reconciled (figure 2.18).

Figure 2.21 CMOc2: Lean Six Sigma and Staff



The staff CMOc again captures the most commonly-occurring findings from the realist review concerning how staff interacted with Lean Six Sigma use within their organisation. Measurement of staff outcomes and testing of this CMOc is facilitated at the study site by the considerable population staff who have led and participated in Lean Six Sigma healthcare initiatives, and who would be willing to engage in this research. A sample can be drawn from 97 Green Belts and 12 Black Belts. The third CMOc identified from the review relates to organisational culture.

Figure 2.22 CMOc3: Lean Six Sigma and Organisational Culture



The organisational CMOc again illustrates the most commonly-occurring findings from the literature review. It illustrates the significant preparatory work that has to be carried out at organisational level to prepare for Lean Six Sigma deployment. This requires top management and leadership support, not just when the outcomes and benefits are realised, but also when the initial hard work of preparation. This has been reflected in the literature.

2.6.3 Summary

This section presented three initial CMOcs developed from the literature. This yielded eleven contextual factors, sixteen mechanisms and nineteen outcomes across the three CMOc. In reviewing the CMOcs, it became evident that within the scope of this research, it would not be possible to address all three through empirical research.

Looking at them in detail and revisiting the literature, a decision was made to focus on CMOc2, Lean Six Sigma and Staff (figure 2.21). The rationale for this was:

1. The outcomes for the CMOc, Lean Six Sigma and Patients, depend, on the CMOc, Lean Six Sigma and Staff, in that staff proficiency and knowledge of Lean Six Sigma are mechanisms for patient outcomes.
2. CMOc3, Lean Six Sigma and Organisational Culture, addresses organisational support; however, the CMOc, Lean Six Sigma and Staff, addresses where and how staff work with Lean Six Sigma in their everyday practice. To truly capture the 'Voice of the Customer', the logical choice for further research was the staff CMOc.
3. Much of the literature talks about organisational gains in relation to KPIs but little refers to how staff feel about their interactions with Lean Six Sigma. As this research is based on the concept of person-centred cultures, there was a need to focus this research on staff as a key component of the impact of LSS.
4. There is a large population of staff who have trained in, led and worked on Lean Six Sigma initiatives, and who are willing to participate in this research

Having developed initial CMOcs from this realist review, this chapter now proceeds to its conclusion.

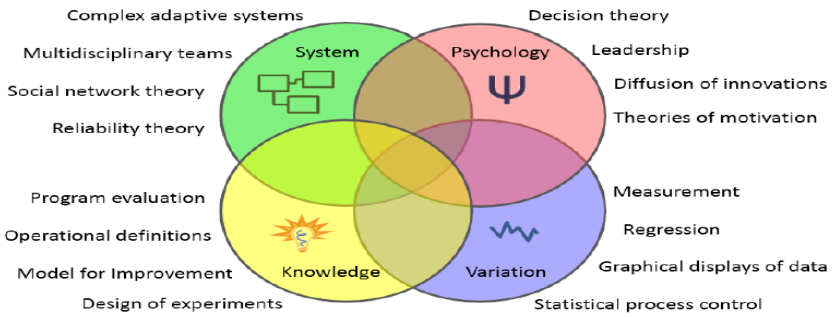
2.7 Conclusion

2.7.1 Introduction

This chapter looked at Lean, Six Sigma, Lean Six Sigma and its deployment or application in healthcare settings. It also looked at person-centred care and person-centred cultures to see where synergies and divergences exist between their philosophy, on the one hand, and Lean Six Sigma methodology, on the other. In discussing the origins of Lean Six Sigma's, this chapter clearly identified that Lean thinking as originally conceived was rooted in the concept of Kaizen and respect for persons. Elements of Six Sigma synergistic with 'voice' and quality were identified that were relevant to this review. Using this approach, and based on the literature reviewed, it was possible to develop a visual representation of the points where Lean Six Sigma is closely orbiting a person-centred care philosophy and could be adapted

for use through a person-centred cultures lens (figure 2.18). The key synergies are around the concept of respect for people (Lean), seeking the 'Voice of the Customer'(Six Sigma), empowering staff (Lean Six Sigma) and observational studies (Lean). It was also demonstrated that there are divergences in first principles and core values of Lean Six Sigma and person-centred care, and also in relation to the potential for rigid insistence on standardisation in Lean Six Sigma. At its heart, Lean Six Sigma is about improving processes. Deming (2000) suggests that any successful improvement in an organisation depends on how well staff are educated and trained in the theory and practice of improvement methodologies and the extent to which they appreciate how their system works in order to better understand variations in a process and how they arise. Deming (2000) also stresses the importance of the psychological dimension or human factors for any organisational change. His System of Profound Knowledge (figure 2.23) captures these four domains and indicates the elements that might be considered in the future development of a model for Lean Six Sigma delivered through person-centred care.

Figure 2.23: The System of Profound Knowledge



Source: Adapted from Deming (2000)

Deming's (2000) model in its recognition of the importance of human psychology echoes Dewing's (2015), and Dewing and McCormack's (2017) model (figure 2.19) which, as discussed, talks about 'patterns' and changing these patterns to develop person-centred cultures. Changing these patterns is dependent on the 'human factors' central to enabling any cultural change. If Lean Six Sigma is to be truly person-centred, then service or process improvement must involve not just staff, but patients

and their family in the design of new care pathways. And it must engage the 'voice' of staff and patients to discover what is 'critical' to them in designing, delivering or receiving care. In addition to identifying the synergy and divergence between Lean Six Sigma and person-centred care and person-centred cultures, this chapter has enabled identification of three initial CMOcs and justified the decision to focus on the CMOc, Lean Six Sigma and Staff, which has informed the next steps in this research.

2.7.2 Next steps

According to Deming (1994), there is an ongoing search for conceptual frameworks that can be usefully brought to bear on process improvement. This realist review has provided an opportunity to deepen understanding of the way in which Lean Six Sigma philosophy and principles can make an impact on person-centred cultures, in theory and then in practice. The initial CMOcs highlight key areas for attention in the study site if Lean Six Sigma is to be brought into a closer relationship with the philosophy of person-centred cultures. This research examines Lean Six Sigma implementation and its impact on person-centred cultures across departmental boundaries at the study site, and more specifically, examines its effects on staff and elicits their perceptions at different levels of analysis (role, unit/ward/department, team). Following this review the next steps were:

1. Engagement with staff who have undertaken Lean Six Sigma education and training and who generate, lead and participate in process improvement initiatives using Lean Six Sigma. The empirical findings from these initiatives assisted in the adjudication of the CMOc, Lean Six Sigma and Staff (detailed in chapter four).
2. Exploration of existing patient outcome data in the study site to help link patient outcomes to the particular Lean Six Sigma interventions.
3. Revisiting and updating this systematic literature review with new and relevant literature as it became available.
4. Analysis of qualitative and quantitative data from 2, 3, and 4 to develop and refine the initial CMOc.

5. Publication of key findings on Lean Six Sigma's contribution to person-centred cultures from this chapter as peer-reviewed journal and conference papers (Teeling, Dewing & Baldie, 2020).
6.

Mazzocato et *a*l (2012) suggest that case studies of Lean Six Sigma do not offer a robust study design to assess contextual differences or to develop CMOcs. Goodridge et al. (2015) suggest that to fully understand how and why process improvement methodologies such as Lean work, theory-driven evaluations must become commonplace. The literature has illustrated the importance of context and how it might influence staff interactions with, and their use of, Lean Six Sigma. This will be important in any future research on Lean Six Sigma, not just this study. This study examines Lean Six Sigma and its contribution to person-centred care and cultures at the study site; however, further research could look at the wider hospital group, nationally and internationally. As hospitals and healthcare facilities worldwide are implementing process improvement programmes in very different contexts, this research into Lean Six Sigma and person-centred cultures is timely and relevant. The system-wide application of Lean Six Sigma in a major university hospital in Ireland has never before been attempted and its sustainability is therefore an important consideration. At the beginning of this research, there was little literature on the Irish context and, while there has been an increase in output, in particular from the study site, more work is still required

This review has highlighted the need for further study on the implementation of Lean Six Sigma in healthcare and its current and potential alignment with a person-centred approach. From the review it seems that it is possible to develop and test an integrated Lean Six Sigma, person-centred care model in practice. Later chapters of this thesis detail how this study sought to establish whether Lean Six Sigma deployment at the study site works, for whom and how, and ultimately if the Lean Six Sigma approach used contributes to developing person-centred cultures. The next two chapters now set out the research design (chapter three) and methods (chapter four) that enabled this.

Chapter 3: Research Design: Foundations

3.1 Introduction

This chapter sets out the rationale for the choice of critical realism as the philosophy underpinning the approach taken to answer the research question - *whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person-person-centred care and cultures*. Lean Six Sigma is a complex intervention when used in healthcare, as it is the combination of two process improvement methodologies developed in industry: Lean, developed in the motor industry (Womack & Jones, 2003; Kollberg et al., 2007; Aherne & Whelton, 2010; Leite & Vieira, 2015) and Six Sigma, developed in Motorola (Proudlove et al., 2008; Antony 2012). This complexity is compounded by the fact that any evaluation of Lean Six Sigma encounters the issue that Six Sigma and Lean have demonstrable differences in their approach and they can be used independently of each other to deliver outputs (Vijaya Sunder, 2013).

Westhorp et al. (2011) suggest that realist evaluation is appropriate when the goal of the evaluation is to learn more about a programme or when the programme has not been evaluated before. The methodological approach chosen for this research is Realist Evaluation as it facilitates analysis of interventions by adjudicating or evaluating programme theories, using both qualitative and quantitative research (Pawson, 2013). Critical realism supports the view that both quantitative and qualitative research work in tandem to offset the other's limitations (Shannon Barker, 2016). Realist Evaluation has been applied in social policy (Pawson & Tilley 1997; Norris & McCahill 2006; Rycroft-Malone & Bucknell 2010), in health and social work practice (Tolson et al. 2006; Regehar, Stern & Sklonsky 2007; Kazi et al. 2008), and more recently, in evaluations of Lean Six Sigma healthcare programmes (Black, 2009; Kinsman et al., 2014; Mazzocato et al., 2010, 2014, 2016). Realist evaluation design is well suited to assess how complex interventions work in complex situations as it facilitates analysis of the causal conditions underlying an intervention and its impact or influence (Westhorp et al., 2011).

Despite some evidence of realist evaluations of Lean, the literature on Lean Six Sigma in relation to person-centredness, person-centred care and/or person-centred cultures has been found to be sparse and methodologically weak, as discussed in chapter two. Therefore, there is little coherent knowledge to inform the planning and implementation of future interventions to support the development of person-centred models of Lean Six Sigma. This research aims to contribute to an understanding of how the use of Lean Six Sigma can influence person-centred care and cultures, for whom and in what contexts. Realist evaluations attempt to understand the multi-faceted nature of complex programs introduced into and implemented in complex social contexts. According to Pawson and Tilley (2001) realist evaluation allows theories about how complex interventions work to be tested and refined, and ultimately aims to generate new knowledge about what works, for whom and in what contexts.

With little work undertaken to understand how Lean Six Sigma influence person-centredness, person-centred care and cultures, it was important to develop theoretical explanations of how it is expected to work and to test these empirically. Realist evaluation provides a coherent methodology to achieve this and supports the use of multiple methods and data to test theory. Whilst other mixed methodological approaches such as action research can and have been combined with realist evaluation (Westhorp et al., 2011), the lack of previous investigation into both Lean Six Sigma and person-centred care and cultures means that there are no explanatory theories to help determine what outcomes to evaluate. This therefore suggested that an evaluation methodology informed by realist evaluation principles would address the gap that had been identified in the literature, and offer the opportunity to develop and test theory, as required for this enquiry.

This chapter first briefly revisits person-centred care and Lean Six Sigma definitions, discussed in detail in chapter two. It then considers critical realism in relation to axiology, ontology, epistemology and methodology. This is followed by a discussion of realist evaluation to illustrate how the intervention will be evaluated in terms of Context, Mechanism and Outcome Configurations (CMOcs). Following this chapter,

a methods chapter (chapter four) sets out the data collection and analysis plan designed to facilitate this research.

3.1.2 Person-centred Care and Lean Six Sigma

McCormack and McCance (2006, 2010, 2017) emphasise that person-centred care is about every person involved in the patient's care, and are clear that the use of the term 'person' in their work encompasses all those involved in what they designate 'caring interactions'. Lean Six Sigma is one of many approaches to process improvement (Jorma et al., 2016). Overwhelmingly, whether seen as a way of thinking (Elliot, 2001), a philosophy (Liker, 2004), or as having a cultural impact (Schonberger, 1996; Bartezzagni, 1999, Henderson et al., 1999), Lean Six Sigma in healthcare involves staff and their patients (Graban, 2012). Drucker (1993) suggests that healthcare organisations are the most complex form of human organisation, with complexity deriving from the confluence of professions (e.g., doctors, nurses, health and social care professions) and other stakeholders (e.g., patients, relatives, corporate functions) frequently with seemingly incompatible perspectives and timelines. Into this mix can be added social programmes, that work through the reasoning and actions of participants or receivers of such programmes. This view of how interventions work and can be evaluated requires a way of capturing and explaining such complexity. Westhorp (2014) claims that social programs are 'real' and have both helpful (positive) and harmful (negative) effects. Lean Six Sigma in healthcare is delivered through social programmes provided to patients and relatives by healthcare staff and any potential contribution of Lean Six Sigma to person-centred care and person-centred cultures must be investigated using a methodology that captures the complexity of the contexts in which these programmes occur. These considerations have influenced the choice of research design.

3.2 Research Design

Research design is a plan for collecting evidence that will be used to answer the relevant research question. Research design selection is a critical factor in planning because it determines all subsequent choices relating to the conduct of the research.

Vogt (2008) suggests that the choice of design is based on how well it addresses the research question and enables the researcher to resolve a research problem. Mills et al. (2006) advise choosing a research paradigm that is consistent with the researcher's beliefs about the nature of reality. A researcher works with an overarching conceptual framework or 'paradigm' that can be viewed as the 'basic belief system or worldview that guides the investigator' (Guba & Lincoln, 1994, p. 105). The term paradigm was first used by Thomas Kuhn (1970) to describe an overall theoretical research framework. Guba and Lincoln (1994) see a paradigm as comprising the trinity of methodology, ontology and epistemology. Essentially, ontology speaks to reality, epistemology speaks to the relationship between the researcher and this reality, and both inform the methodology used by the researcher to explore that reality. A key issue for researchers is the identification of their research paradigm.

3.2.1 Realism

'Realism' is a philosophy of science that holds the position that reality exists independent of the researcher's mind; there is, in essence, an external reality (Bhaskar, 1978; Harre, 1978). According to Wong et al. (2013), realism is located between positivism (there exists a real world that we can see and understand through direct observation) and constructivism (we cannot know with certainty what the nature of reality is as it has been interpreted through our senses and our brain) and as such avoids these traditional epistemological poles. Wong et al. (2013) explain realism's location between positivist and constructivist philosophies by characterising it as accepting of a real world processed through our human senses while arguing that our understanding of the real world can be improved because it constrains the interpretations that we make about it. Realists recognise the differences between the real world and their own view of it and, according to Riege (2003), try to construct views that are relative in time and in place. Structures in social science can therefore be linked to the experiences that the researcher has in the field. These experiences will be subject to contingent contexts and to different reflective participants (Pawson & Tilley, 1997). Wong et al (2014) acknowledge that whilst the researcher's knowledge will always be partial, it can accumulate over time.

Realism has two distinctive branches: empirical realism, where reality is constrained to the observable (Pawson 1989, Williams 2000, Carter & New 2004); and critical realism (Bhaskar, 1975, 1978, 2002, 2008; Archer 1995; Archer et al., 1998), where reality is not just the observable, but is understood at a deeper and more complex level. Empirical realism claims that the researcher can understand reality through the use of appropriate methods (Bryman, 2012), sometimes described as the 'naive' approach, holding that there is a very close alignment between reality and the terminology used to describe it. Bhaskar (1989) claims that empirical realism fails to understand the role of underlying structures and mechanisms in generating observable events unlike critical realism that not only understands their importance but also seeks to identify them through social scientific inquiry. Pawson (2006) notes that empirical realism is variously described as scientific, emergent, or analytic realism (amongst others).

The critical realist distinguishes the 'real' from the 'actual' and also from the 'empirical'. The real consists of underlying, causal or generative mechanisms that are not observable. The actual refers to events caused by, or manifestations of, these underlying mechanisms that are observable but may not necessarily be observed (for example, the expression of a gene in hair colour is observable and observed but not all expressions of genes are observed). The empirical refers to that which is directly experienced or observed (for example, the colour of someone's eyes). To sum up, empirical realism entails a more descriptive approach with a close correspondence between 'reality' and the terminology used when describing it, while critical realism seeks to identify underlying causal or generative mechanisms that give rise to actual events, some of which can be experienced or observed. The development of critical realism was in part a response to problems of research based on realism (ontology) and positivism (epistemology) (Bhaskar, 1975; Archer et al., 1998).

Sayer (1992) and Pawson and Tilley (1997) state that realists acknowledge the stratified nature of social reality, recognising the embeddedness of all human action within other social processes. Social stratification implies the arrangement of any social group or society in which positions are hierarchically divided. Critical realists seek to understand and describe how social interactions, reasoning and actions are

shaped by and shape the social world and this stratification of social reality (Pawson, 2006). For critical realists, causal powers reside not in specific objects or particular people but in the social relations and structures they constitute. Specific actions are considered to be mechanisms fired as a result of particular interventions in social worlds and giving rise to certain effects. Mechanisms therefore effect the outcomes achieved by people working in social worlds and influence the outcomes achieved by any improvement programme involving them. Pawson and Tilley (1997, 2006) claim that whatever the intervention, it will only work as intended if the subjects actually go along with the programme theory. Here, Pawson and Tilley imply that programmes only work if people actually choose to make them work; however, the realist researcher must be mindful that not all decisions that people make are chosen or even conscious. The realist researcher must also remain cognisant that reasoning is influenced by the socially stratified nature of the individual's context and therefore the context can influence the likelihood that the programme theory will work as predicted.

The challenge for the realist evaluator is to understand the stratified social world, not through their own perceptions, but through those of the participants (Pawson & Tilley, 1997). Consequently, ontologically, a realist approach requires the realist evaluator to accept that both participants and programmes are based in stratified social reality that is independent of the researcher (Marchal et al., 2012). To a realist, interventions are therefore seen as theories, which hypothesise that, if delivered in a certain way, in particular contextual circumstances, a programme will generate a particular outcome (Pawson & Tilley, 1997). Pawson and Tilley (1997) also see interventions as complex interactions within macro and micro social processes, between individuals and institutions. Pawson (2006) claims that what constitutes realist work is an understanding of key aspects of social science, including causation, the nature of the social world and the stratification of social reality. To clarify how the realist approach works in practice, there is expansion on the concepts of intervention, mechanism, context and outcomes in detail later in this chapter. Before then, questions of axiology, ontology and epistemology are addressed.

3.2.2 Axiology, ontology and epistemology

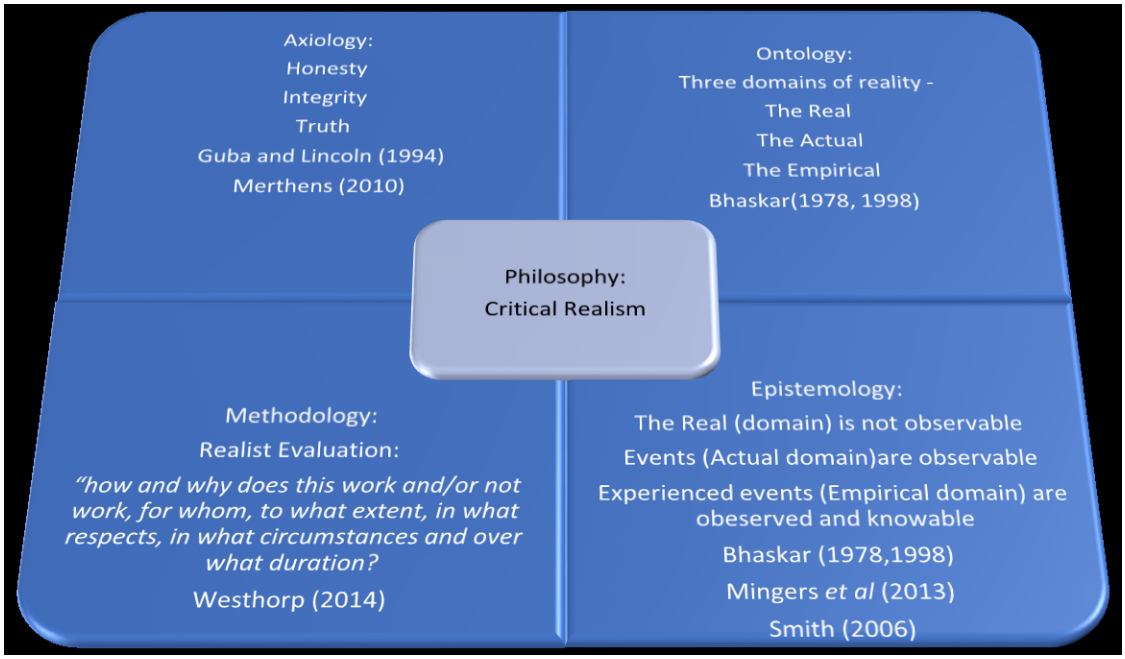
Rosenthal (1967) defines axiology as the branch of philosophy, dealing with quality or value, with Chopra (2005) seeing it as the component of philosophy that studies judgements that relate to values. In research, axiology relates to the researcher's beliefs about what is ethical and valuable (Killam, 2013). Therefore, as the researcher it is important to articulate my personal beliefs and values, which are rooted in integrity, honesty and truth. Merten (2010), and Guba and Lincoln (2004) emphasise the importance of the researcher making axiology explicit to help guide and promote rigour in their research. Axiology informs my ontology as a researcher, with ontology considered to be the researchers view of reality and being, whilst epistemology can be viewed as the processes by which the researcher believes they acquire and develop knowledge. Blaikie sees ontology as

> claims and assumptions that are made about the nature of social reality, claims about what exists, what it looks like, what units make it up and how these units interact with each other. In short, ontological assumptions are concerned with what we believe constitutes social reality. (Blaikie, 2009, p. 8).

Crotty (1998, p. 3) defined epistemology as 'the theory of knowledge embedded in the theoretical perspective and thereby in the methodology'. Blaikie (2009, p. 8) sees epistemology as 'the possible ways of gaining knowledge of social reality, whatever it is understood to be. In short, claims about how what is assumed to exist can be known.'

Together, the researcher's ontological and epistemological assumptions constitute the paradigm. Critical realism represents my personal ontological and epistemological position. This is outlined in figure 3.1 alongside the research design chosen for use in this study, Pawson and Tilley's (1997) realist evaluation methodology.

Figure 3.1: The approach to this research



According to Mingers (2004):

> Critical realism asserts that the conditions for knowledge do not arise in our minds but in the structure of reality, and that such knowledge will not be universal or ahistorical. (Mingers, 2004a, p.92).

The critical realist therefore attempts to dive beneath the surface so to speak, to begin to understand and subsequently explain events by hypothesizing about social structures and mechanisms. Critical realism endeavours to identify structures that generate the social world in order to locate them in the domain of the actual. Ontologically, critical realism can be seen as the least restrictive perspective (Bhaskar & Danermark, 2006) for the researcher, being

> maximally inclusive as to causally relevant levels of reality and additionally maximally inclusive insofar as it can accommodate the insights of other metatheoretical perspectives. (Bhaskar & Danermark, 2006, p. 294).

In other words, critical realism combines a realist ontological viewpoint (the individual's acceptance of a real world that exists outside their own perceptions and hypotheses) with the epistemological approach of the interpretivist (the individual's understanding that the world is ultimately shaped by their own perspective). Guba and Lincoln (1994) suggest that ontology seeks to understand the form and nature of reality by questioning. Critical realism's basic ontology suggests that there are three layers of reality (Blaise & Kegels, 2004; Black, 2009); namely:

1. Structures, mechanisms, power and relations
2. Actual events and actions taken
3. Experience of events and actions

Critical realism is, according to Creswell (2011), cognisant of a world that is based on the individual's perceptions but Maxwell and Mittapalli (2010) see this as contextualised within a realist ontology that recognises that there is a world outside our perception and that realities exist that simply cannot be known (Guba, 1990). Realism therefore implies that individuals construct meaning in interaction with a real world, and that critical realist researchers endeavour to measure and validate what Bisman (2010) calls underlying structures in reality.

Whilst theories, concepts and perspectives may generate a valid understanding of a phenomena, they cannot and do not exhaust it, as all knowledge is contextual and partial; other conceptual schemas and perspectives are always possible and theories, concepts and findings are grounded in values and perspectives (Altheide & Johnson 2011). Research in this tradition focuses on the identification and explanation of the underlying generative mechanisms that shape structure, agency and the social relations that are reproduced and/or transformed (Reed, 2005). Therefore, a theory of the experiences of healthcare staff of any contribution of Lean Six Sigma to person-

centredness, person-centred care or person-centred cultures will generate understandings of the topic, but the researcher must acknowledge that these can never be definitive given that all knowledge is contextual and partial. The generation and exploration of data will, however, enable further testing of emergent hypotheses and therefore enhance our understanding of how and in what circumstances Lean Six Sigma contributes to person-centredness, person-centred cultures and person-centred care. The limited literature on Lean Six Sigma and person-centeredness (chapter two) alludes to this but acknowledges neither the importance of context nor that its findings are grounded in values and perspectives. Epistemology considers the nature of the relationship between the 'would be' knower and what can be known (Guba & Lincoln 1994). The answer to the epistemological question is always constrained by the answer to the ontological question. What can be known about any social programme is never definitive.

3.2.3 Ontological Position

Having located my own ontological and epistemological approach, it is important to illustrate how this informs the rationale for this research design. Tilly (2008), in a discussion of social processes, suggests emphasis should first be placed on ontology, rather than epistemology. The identification of the researcher's ontological position, is important as

> social analysts frequently arrive at false conclusions by assuming the existence of fundamental entities such as social systems without doing the work required to establish the presence of those entities. (Tilley, 2008 p. 5–6).

Ontology can be seen as 'the study of being' (Crotty, 2003) concerned with what kind of world we are investigating, with Guba and Lincoln (1989) viewing ontological assumptions as those that respond to the question 'what is there that can be known'. Healy and Perry (2000) suggest that ontology is the 'reality' under which the research is located. For this research, the ontological positions that explain the choice of research design are:

- Individuals in different social contexts will experience Lean Six Sigma methodology differently from each other and so multiple perspectives are important to the research.
- Similarly, individuals in different social contexts will experience person-centred principles differently from each other. Multiple perspectives allow comparisons to be drawn between contexts, offering reasons for any variation in outcomes associated with Lean Six Sigma across systems. Researching any changes in individuals' views of person-centredness, person-centred care and person-centred cultures through their interaction with Lean Six Sigma requires a research design that is cognisant of underlying causative factors. Realist evaluation facilitates this through the identification, examination and adjudication of CMOcs in practice settings.
- Social structures are, according to Bhaskar (1979), 'localised in both space and time' and will not be retained in some cultures or sub-cultures indefinitely; therefore, I as a researcher can never know everything.
- People's perspectives are only one window through which an intervention's impact can be examined. Multiple data sets can help determine how an intervention operates and reasons for its varying impacts across different social contexts.

Given that in the role of the researcher I accept that individuals react to the world differently and that this is often mediated by contextual factors in the socially stratified worlds they exist in, it is my hypothesis that causative factors exist in the world that may affect individuals' perceptions of Lean Six Sigma's influence on person-centredness, person-centred care and person-centred cultures within their organisation. From an ontological position, this helps determine what works for whom, in what circumstances and in what conditions (Pawson, 2013) from the individual perspectives and realities of UCD's Lean Six Sigma programme graduates involved in Lean Six Sigma process improvement.

3.2.4 Epistemological Position

Having identified my ontological position, I now discuss my epistemological position, which according to Crotty (2003, p. 3) is 'a way of understanding and explaining how we know what we know' and, is consequently, an important factor in the research process. When researching social phenomena, context is important both for the choice of methodology (Guba & Lincoln, 1994) and for methods (Carter & Little, 2007). Lean Six Sigma process improvement programmes are delivered in 'real world' university and clinical settings with broad social goals such as education, population health and wellbeing. Kent and Tsang (2011) suggest that critical realism proposes a realist ontology, interrelated with a fallibilist epistemology in which the researcher's knowledge of the world is socially constructed. A fallibilist epistemological approach is one in which the researcher recognises that no belief (theory, view, hypothesis) can ever be rationally supported or justified in a conclusive way; there is always doubt as to the veracity of any belief (Hetherington, 2013). This epistemological approach recognises that all observation is fallible and subject to error (Trochim, 2006), whilst accepting that reality is 'real', but not perfect, and that findings are often true. This has synergies with evaluation theory that, while cognisant of concepts of truth and certainty, is more concerned with developing an understanding of the reality of delivering complex social programmes to ascertain their value in use (Clarke & Dawson, 1999). In his review of the work of Bhaskar (1975), Fleetwood (2014) sets out the key assumptions of a critical realist epistemology:

1. There is an emphasis on ontology before epistemology.
2. Knowledge is fragile—for epistemological reasons.
3. Knowledge is derived from finding causal mechanisms.
4. The 'truth' is difficult but not impossible to uncover

This research takes a critical realist epistemological approach, and seeks to develop answers to underlying research questions informed by the work of Pawson and Tilley (1997) and their CMOc model; i.e., what are the underlying causative mechanisms (M = mechanism) that operate in the 'real' world (C = context) and help capture the extent to which an intervention works (O = outcome). This study seeks to understand how

and in what circumstances Lean Six Sigma does or does not contribute to person-centredness, person-centred care and person-centred cultures. Having discussed my epistemological approach, the discussion now moves to realist enquiry.

3.3 Realist Inquiry

Pawson, Greenhalgh et al. (2005) suggest that realism is not a research method but a methodological approach for the development and selection of research methods. According to Bhaskar (1978, 2005), realist inquiry is based in the realist tradition of the philosophy of science and social science. Realist inquiry seeks to develop a common understanding of underlying factors and causative mechanisms and, according to Pawson (2006), seeks to understand the components of the social world and stratifications of social reality. Traditional orthodox research strategies such as systematic reviews look for the answer to the question 'what works?' In realist inquiry there is a focus not only on 'what works' but on 'what works for whom, why it works, and in what circumstances' (Pawson et al., 2005; Pawson, 2006). Within realist inquiry, two approaches have come to the fore: realist evaluation and realist review. Realist evaluation is a form of inquiry utilised for primary research and involves the collection of data from the source. Realist review, sometimes known as realist synthesis, is a companion research approach, involving the analysis of existing data including stakeholders views and opinions. There follows elaboration on each.

3.3.1 Realist Evaluation

Realist or realistic evaluation (realist evaluation) was developed through the work of two British sociologists, Ray Pawson and Nick Tilley (1997) and has its roots in the work of Bhaskar (1975) and in the realist philosophy of science (Porter & O'Halloran, 2012). Realist evaluation's ontological view is based on Bhaskar's (1975) philosophy of critical realism, which posits that the world is complex and needs to be understood at different levels of human interpretation that move beyond biology or physics to focus on the human dimension. Realist evaluation is, according to Pawson and Tilley (2001), an evaluation approach that is has roots in realist epistemology, placing importance on providing explanations for phenomena and suggesting that knowledge can be developed from combining such explanations. Pawson and Tilley's (1997) work

on ‘realistic evaluation’ was a defining moment in their research; however, it is now known more often as ‘realist evaluation’. Although there are many schools of realism, Pawson and Tilley (1997) termed their approach as ‘scientific realism’. Tilley’s (1993) initial work looked at the impact of CCTV use in car parks on crime rates, demonstrating that a hypothesis as to why CCTV might make an impact on crime and a theory concerned with the conditions that enable this impact were required to generate any conclusions. Use of realist evaluation was therefore seen as providing a generic method of evaluation applicable to social life where interventions such as policy, legislation, projects, new processes are applied in existing social settings such as law enforcement, healthcare and education. This indicates that the use of realist evaluation is appropriate for this study. The NHS Service and Delivery Report (Greenhalgh et al., 2004) advocated a realist evaluation approach to system-wide research and this has led to large volume of healthcare studies (>100) using realist evaluation (Priest, 2006; Black, 2009; Greenhalgh et al. 2009, 2012; Best et al., 2012; Wong et al., 2010, 2012; Williams et al., 2013; Rycroft Malone et al., 2016). Realist evaluation shuns more conventional approaches to evaluation and focuses on determining what evidence is actually comprised of and how value is determined. Pawson and Tilley (2001) see realist evaluation as a theory-based evaluation designed to test and refine the theory that has informed the development of multiple and varied programmes or interventions. Pawson (2002) further sees realist evaluation as a form of theory-based evaluation specifically developed to strengthen the explanatory power of evaluation studies. Theory-based evaluations are, according to Hansen (2005), unlike result and process evaluation models as they are concerned not only with outcome measurement but also with identifying any processes and contexts that support those outcomes. Indeed, Lean Six Sigma looks at linear before and after trends and patterns when evaluating process improvements. Pawson (2013) reiterates the importance of the realist evaluator understanding that realist evaluation has less of a focus on whether an intervention worked but rather is concerned with how it worked. This includes:

- Ascertaining what works for whom in what circumstances?
- Capturing all conditional factors

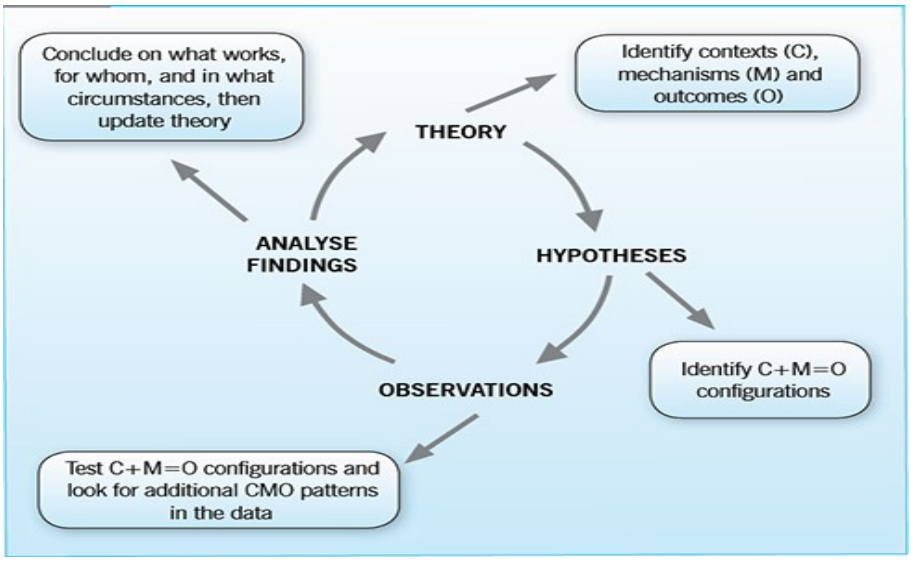
- Understanding that it is people who make programmes work
- A recognition of the complexity of social programmes

(Pawson, 2013)

Realist evaluation's aim to understand 'what works, for whom, in what circumstances and why' (Pawson & Tilley, 2007) means that, rather than providing judgements on a programme's success or failure, there is an appreciation that underlying causative factors must be understood. This underlying focus of realist evaluation recognises the explanatory power and contribution to knowledge of 'generative causation' through the first principles of CMOcs (Pawson & Tilley, 1997).

Realist evaluation's epistemological view means it is the role of the researcher to test theories to identify what works for whom in what circumstances. CMOcs comprise the Context (C) that denotes a wide range of conditions that affect any programme. The variation in response of individuals to the programme will be dependent on factors such as their own understanding of what they can do, and what they need to contribute (Pawson & Tilley, 1997); this is known as the Mechanism (M). The hypothesis as to the programme outcome (O) theorises about the programme's results. The Context, Mechanism and Outcome is often expressed in the formula C + M = O (CMO), with configurations (c) of multiple CMOs generating the term CMOcs (figure 3.2). Pawson and Manzano-Santaella (2012) claim that each configuration is a hypothesis that the programme outcome (O) occurs due to underlying mechanisms (M), understood as the interplay of resources and reasoning, which are activated only in certain contexts (C). Realist evaluation is concerned with the various combinations of underlying factors at work in programmes that cause outcomes. Pawson (2002) suggests that realist evaluation is not so much a technique for evaluation as a framework for programme evaluation. Hypotheses as to what works for whom in what circumstances are tested through observation, and it is the observation that leads to programme specification about what actually works and this in turn is used for initial hypothesis refinement. Pawson (2006, 2012) claims that following the initial CMO, each subsequent iteration and configuration, informed by empirical data, refines the original programme theory.

Figure 3.2: Context Mechanism Outcome in Realist Evaluation



Source: Taken from Linsley et al. (2015, p29)

The component parts of the CMOc are elaborated on later in this chapter. From the point of view of the use of realist evaluation to address this study's research question, there is strength in the fact that it draws on multiple sources of evidence using both quantitative and qualitative approaches. The realist evaluator must be aware of and reflect on the perspectives of all programme stakeholders and focus on understanding the relationship between the stakeholder and the programme. Pawson and Tilley (1997) suggest that the researcher who uses realist evaluation is challenged to understand the social world as perceived by the actual programme participants. This understanding is vital to an understanding of Lean Six Sigma's impact and influence on person-centredness, person-centred care and person-centred cultures. One of the strengths of realist evaluation is its focus on generative mechanisms where causation is seen as acting internally as well as externally. This means that the goal of research is not just to study outcomes (effects) but to explain why causal outcomes follow from mechanisms acting in contexts. There now follows discussion of realist review or synthesis.

3.3.2 Realist Review

The process of synthesising data from existing studies is known as 'meta-analysis' (Pawson, 2006), which in many cases 'measures the measurable' (Wong et al., 2012). Realist review, also known as realist synthesis, has exactly the same objective as realist evaluation; that is, programme theory refinement (Pawson et al., 2004). It was developed by Pawson (2005) to examine existing data to better understand complex problems. Wong et al (2012), suggest that complex problems comprise:

- Numerous interacting components within an intervention
- Numerous behaviours demonstrated by those involved in an intervention
- Number of groups involved in an intervention
- Variability and number of outcomes
- Allowance for flexibility
- Non-linear patterns
- Reliance on people
- Context dependency

Pawson (2006) claims that the differences between a standard meta-analysis approach and a realist approach are significant (table 3.1). This is why the approach to analysis is fundamental to the choice of research design.

Table 3.1: Meta-analysis vs. Realist understanding

Meta-Analysis Perspective	Realist Understanding
Programmes have effects	Programmes are theories
Evaluation measures effect sizes	Evaluation is theory testing
Systematic review seeks mean effect	Systematic review is concerned with theory-synthesis

Source: Adapted from Pawson (2006)

Realist review involves analysis and interpretation of existing data. In essence, it is the application of the realist approach to retrospective literature reviews (Pawson, 2002),

which was detailed in chapter two. Realist review acknowledges that theories cannot and do not always offer explanations or predict outcomes in every context; for example, in patient safety programmes (Newton et al., 2011). Realist review encompasses reviews of existing studies that use a wide range of research and evaluation approaches and, as with realist evaluation, it has no particular bias towards either quantitative or qualitative methods. Wong et al. (2012) see realist reviews in the context of the 'what works, for whom, in what circumstances' approach as being non-judgmental and explanatory and, whilst borrowing some ideas from traditional systematic reviews, they are more iterative, testing and building theory. Based on Pawson's (2005) work, and the interpretation of that work by Velonis et al. (2016). we can identify a five-step approach to realist review:

1. Agree the scope of the review and identify hypotheses that will explain mechanisms that are causative factors in change.
2. Identify a start point to search for evidence.
3. Review primary studies and retrieve data.
4. Synthesize evidence and develop conclusions.
5. Refine theory iteratively and disseminate findings.

A realist review of relevant literature applicable to the research question *whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person-centred care and person-centred cultures*, is presented in chapter two and identifies three initial CMOcs. For the researcher seeking to understand context, both realist evaluation and realist review emphasise the importance of understanding and explaining circumstances that are context specific as well as the mechanisms that lead to the outcome of an intervention. The components of both realist evaluation and realist review are now discussed.

3.3.3 Components of Realist Evaluation and Realist Review

Both realist evaluation and realist review comprise a number of component parts that need to be elaborated to understand realist research methodology. Understanding how

and why an intervention works by developing hypotheses about the anticipated outcomes of that intervention is what Pawson et al. (2005) term 'programme theory'.

Component 1: Intervention

Realist evaluation focuses on interventions. Understanding the intended outcomes of the intervention is important as, according to Herepath et al. (2015), some previous applications of realist inquiry in health care have had inconsistent application of the concept of intervention and, if underspecified, the intervention can be conflated with context. However, there is a growing body of work using realist inquiry to analyse interventions within healthcare organisations (Manzano-Santanella, 2011; Greenhalgh et al., 2012) including those using Lean Six Sigma methodology (Mazzocato et al. 2012, 2014, 2016). In this research, the intervention has been identified as the UCD Lean Six Sigma education and training programme for staff (chapter one). This programme is designed to enable individual, organisational and system change, and interventions of this type are known for their complexity (Pawson et al., 2011a; Pawson et al., 2011b; Wong et al., 2011). Wong et al. (2013) emphasise that it is not the intervention that causes outcomes; rather it is the participants' reaction to opportunities inherent in the programme that are the catalysts for change. The realist researcher consequently looks for interactions between the understandings and responses of participants and the opportunities inherent in the intervention. Intervention implementation is, however, not without its difficulties as it is influenced by both individual and group interactions within social systems, which have a subsequent impact of the success of any programme (Wong et al., 2010). Wong et al. (2010, 2012) therefore claim that the actualisation of any particular intervention is dependent on the context of the social system into which it is introduced. Wong et al. (2009, 2012) suggest that interventions are multifaceted, with different organisations having their own contextual enablers. In this context, Wong et al (2016) stress the importance of initial programme theory development that sets out how and why an intervention (such as the Lean Six Sigma education and training programme) is understood to work to generate outcomes of interest. This leads to discussion of programmes and programme theory.

Component 2: Programmes

An initial programme theory can be developed from previous research work, existing knowledge, experiential learning and, according to Pawson (2006), the underlying assumption of the intervention designers that if the intervention is delivered in a certain way it will lead to improvement. It is important in realist evaluation to understand the necessity of making the programme theory explicit, with the initial programme theory outlining how and why an intervention is assumed to work to generate outcomes. However, the programme theory is not always obvious, and the realist evaluation approach is based on making it explicit. Pawson and Tilley (2004) suggest that when using realist evaluation there is a cyclical return to underlying theory or theories of how a programme works, and subsequent cyclical re-evaluation of the theory or theories. Within realist evaluation, programmes are seen as embedded, active and grounded in theory. Each of these characteristics is discussed in turn.

1.Embedded

Programmes are embedded in pre-existing social situations. In this research, participants are UCD Lean Six Sigma graduates, utilising Lean Six Sigma within their daily work and social situation. Pawson and Tilley (2004) see interventions as being dependent on contexts such as individual capacity, interpersonal relationships, institutional balance and infrastructure. Part of this research was concerned with identifying important contextual factors that shape the Lean Six Sigma programme, how practitioners engage with it and its influence on person-centred care and person-centred cultures.

2.Active

Awareness is maintained that intended programme effects work through the understanding and accord of individuals. The role of the individual is important, with Pawson and Tilley (2004) suggesting that effects are generally produced by and require active engagement from individuals. Wand et al (2011) suggest that it is not the interventions themselves that enable complex social interventions to work, but the reaction and reasoning of the individuals involved. *Within this research there was*

cognisance that participants' intentions, values, ideas and activity shape their response to the Lean Six Sigma programme. And that many of those variables are influenced by the social context in which they work.

3.Theory

Generally, realist evaluations begin with an initial programme theory (hypothesis) and end with a more developed theory. Birckmayer and Weiss (2000) suggest that programme theories can be seen as the set of assumptions of the programme designers and others involved in the programme that explain their expectations of the intervention in achieving its objectives. The first step in conducting realist evaluation is, therefore, to develop the programme theory to explain how the proposed intervention is expected to work in the eyes of the programme designers and implementers (Pawson & Tilley, 1997). The initial programme theory of this research is that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD education and training programme (chapter one). Empirical testing through a realist review involved the identification of CMOcs as an analytic instrument to help build and refine the programme theory (Pawson & Sridharan, 2009). This led to first refinement of the programme theory. Initial CMOcs are detailed in chapter two and are further evaluated through data collection in chapter four to determine what in the intervention works for Lean Six Sigma graduates, in what circumstances. Following a complete realist evaluation cycle, the researcher obtains a refined version of the initial programme theory that can then be tested through multiple realist evaluation cycles to further refine it. Pawson and Tilley (2004) believe that a realist approach has implications for both the evaluation design and its participants. As opposed to a Randomised Control Trial (RCT) entailing a comparison of changes for participants who have undertaken a Lean Six Sigma education and training programme with those who have not, realist evaluation compares mechanisms and outcomes within the actual programme. The complexity of programme theory cannot be underestimated, and Pawson (2013) identified a mnemonic, VICTOIRE, to help identify the high-level factors that contribute to it:

- **V**olition: the understanding and knowledge of stakeholders
- **I**mplementation: the implementation pathway
- **C**ontexts: e.g., location, participants' characteristics
- **T**ime: the temporal location and duration of the intervention
- **O**utcomes: understanding that there may be multiple outcomes
- **R**ivalry: competition with other programmes
- **E**mergence: how effects develop and emerge from the programme.

Pawson and Tilley (2004) believe that any programme is formed, blocked or enabled by such a complexity of multifactorial variables that any evaluation is always likely to be provisional, ambiguous and uncertain. Realist evaluation offers an appropriate methodology for evaluating improvement initiatives such as Lean Six Sigma that explicitly acknowledges and works with this ambiguity and uncertainty. Instead of asking 'has this initiative (Lean Six Sigma) worked?', the researcher is asked to consider, and evaluate, what is going on in a particular initiative (Lean Six Sigma) that is worth sustaining and developing (in this case, any contribution to person-centredness, person-centred care and person-centred cultures). Realist evaluation offers an evaluation framework that focuses on contextual factors and outcome patterns, while allowing the researcher to identify those mechanisms that trigger effects that we would judge to be worth continuing (NHS Leadership Academy, 2014) and those contextual issues that need to be addressed because they prevent certain mechanisms contributing to positive outcomes. Identifying mechanisms within the Lean Six Sigma intervention that promote person-centred care and a person-centred culture is therefore a key focus of this research.

Component 3: Mechanisms (M)

The concept of an underlying or generative mechanism is a key factor in discerning what it is about programmes and interventions that generate effects (Pawson & Tilley, 1997; Pawson 2006, 2013). Mechanism is defined as understanding 'how' participants interpret, interact with and act upon interventions, and the processes by which they do so (Pawson & Tilley, 1997; Pawson, 2006, 2013). Pawson and Tilley (1997) use the

term mechanisms to refer to how measures are supposed to act; i.e., how individuals reason and then act, and explain that a key focus for evaluation is to find out whether the hoped for mechanisms actually functioned as people believed they would.

In realist evaluation it is understood that the mechanism has a direct relationship with causation. Processes that produce events, or patterns of events, can be seen as causal mechanisms. Pawson (2006) asserts that mechanisms offer explanation of causal relationships by describing both the understanding of participants and the resources available to the social programme. Jagosh et al. (2012), whilst also claiming that mechanisms offer explanations of causal relationships, note that they are associated with but not suggestive of the programme theory. This is important, as realists must therefore make explicit which concept of mechanism they are using in their work. Fleetwood (2005) also notes the causal nature of mechanisms, suggesting that they comprise clusters of causal factors or are composed of myriad facets of the social world. For Pawson and Tilley (1997), the social world

> is the prior set of social rules, norms, values and interrelationships gathered in these places which sets limits on the efficacy of programme mechanisms.
> (Pawson & Tilley, 1997, p.70)

Westhorp (2015) suggests that, if you are not a realist, your assumption is that context affects outcomes. However, the realist realises that context effects mechanisms which in turn influence outcomes. Chapter two identified the mechanisms that are predicted to enable positive outcomes for study participants and their colleagues from the intervention of a Lean Six Sigma education and training programme. The concept of context within realist evaluation is now discussed.

Component 4: Context (C)

Identification of programme mechanisms is the first step in realist evaluation; however, the realist researcher understands that mechanisms can only be active in particular contexts or under a certain set of circumstances. Realist evaluation emphasises the importance of context in trying to understand how complex

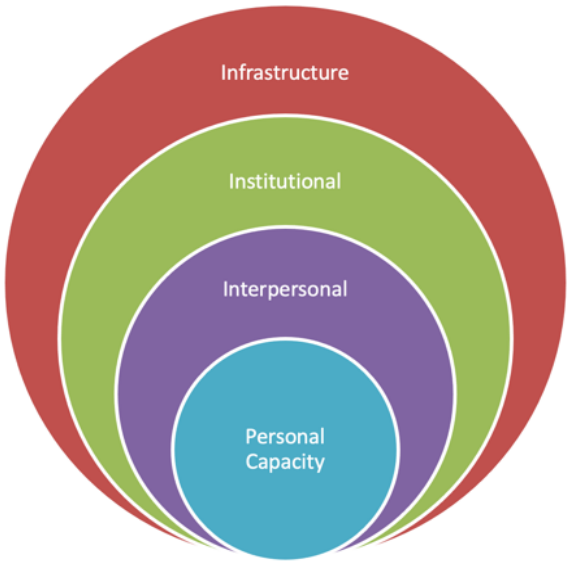
programmes lead to changes in outcomes. Pawson and Tilley's (1997) interpretation of contexts is closely aligned to human activity and intentions; some examples researchers may encounter include:

- A manager's willingness to support a new initiative (e.g. Lean Six Sigma education and training);
- Students' and colleagues' enthusiasm for new initiatives (e.g. Lean Six Sigma education and training);
- The influence of ideas and practices such as evidence-based design, Lean or distributed leadership in an organisation (NHS, Leadership Academy, 2014).

This focus on human activity highlights the importance of social contexts in understanding how complex programmes lead to changes, and is a distinctive feature of realistic evaluation (Blamey & Mackenzie, 2007). Drucker (1993) recognised the complexity of healthcare organisations as human and social organisations, and Bonner (2003) regards as paramount an awareness of people's role in generating change through actions based on their interpretation of an intervention, their own capability and limitations.

Realist evaluation uses contextual thinking to address the question, for whom and in what circumstances a programme works. Pawson (2006) claims it is not possible to establish a potential correlation between an intervention and an outcome without first identifying any pre-existing contextual factors (contexts). In Pawson's (2006) opinion, in realist evaluation, mechanisms work in tandem with contexts in a causal manner to deliver outcomes. Realist inquiry stresses the importance of context (Pawson, 1997) but a realist is aware that interpretation of context must not be limited to the geographical, spatial or institutional location of that context; rather, context must be analysed and understood in its full complexity (Pawson & Tilley, 2001). Pawson (2006) identified four concentric layers of context (figure 3.3).

Figure 3.3: Contextual Layers



Source: Adapted from Pawson (2006)

The outer layer is identified as infrastructural systems encompassing, for example, politics, economics, regulation and legislation, followed by the cultural aspects or ethos of the institutional setting, the interpersonal relationships between the individuals in this setting, and then the inner layer of individuals' capacities (Pawson, 2006). The identification of these layers or domains is important in reminding the realist researcher that a consideration of context should not be limited to a specific domain and the importance of identifying which domain is most influential in particular research settings (Dixon Woods et al., 2010; Löfgren et al., 2012). Realist evaluations that encompass these four domains have been undertaken in healthcare settings, by both clinicians and managers (Dickson Woods et al., 2011; Francis, 2013) and using patient-informed performance evaluation (Turner et al., 2013). Pawson and Tilley (1997) are clear that, whatever the relevant contextual domain, there is no expectation that major contextual change will occur during or because of a particular programme.

However, recognising and accommodating context is essential for a successful social programme that ultimately aims to change behaviour (NHS Leadership Academy, 2014). If the contextual domains are not amenable to the programme, then the programme's mechanisms will either not be triggered or will not fully engage participants, and there will, therefore, be little or no effect on the current state. Pawson and Tilley (1997) use the analogy of gunpowder, where a spark in its vicinity will cause an explosion. However, no explosion will occur if the conditions are not exactly right; no oxygen for the spark, not enough gunpowder, or gunpowder that has become damp (Pawson & Tilley 1997). Similarly, in this research, there is a need to identify the social and cultural conditions necessary for any outcome related to person-centredness, person-centred care or person-centred cultures from the intervention of the Lean Six Sigma programme to be realised.

In working with CMOcs, as a researcher I am cognisant of the importance of not confusing context with mechanism and vice versa. Archer's (1995, 1996) socialist realist theory recognises that confusion can exist between context and mechanism and is clear that they are separate entities. Archer (1995, 1996) suggests that problems with distinguishing context from mechanism, which she feels is problematic, are in part due to lack of consistency and clarity in the way that context is conceptualised. Pawson and Manzano-Santaella (2012, p.189) also warn that 'programmes do not come in pre-ordained chunks called contexts, mechanisms and outcomes' and that it is unhelpful in realist evaluation to assume that they do. In undertaking this research, whilst clearly identifying the UCD Lean Six Sigma education and training programme as the intervention, care was taken not to assume underlying contexts and mechanisms that may generate particular outcomes in relation to person-centred care and person-centred cultures. The discussion now moves to Outcome.

Component 5: Outcome (O)

Realist inquiry does not rely on a simplistic single outcome measure to decide if a programme is judged as a success or failure. The realist researcher rather looks for outcome patterns that comprise both the intended and unintended consequences of programmes, which result from different mechanisms and different contextual factors.

Outcome patterns make explicit the sequence and the timescale of actions, allowing an analysis of what happens before, during, after or as a result of another occurrence (NHS Leadership Academy, 2014). Traditional evaluation approaches attempt to estimate programme effectiveness through the assessment of programme outcomes (Pawson & Tilley, 2004; Connelly et al., 2007; Hewitt et al., 2012). This approach to evaluation, sometimes called 'black box evaluation' (Scriven, 1994), focuses on outcomes without seeking to understand how the outcome was achieved. Pawson (2006) claims that the chance of a social programme actually working is completely dependent on the variable of the people involved in the programme, their alignment with the reasoning behind it and their use of the provided resources as intended. It would be simple, for example, to attribute healthcare outcomes for patients attending an Emergency Department to a government social programme that provides increased funding; however, this takes no account of contextual issues such as staff morale, sick leave, competency or attitudes as to how the money is spent. Although this particular social programme is offering a resource (money), Pawson and Tilley (1997) and Pawson (2006) reiterate that it is the interaction of the agents (e.g., healthcare staff) with the resource that results in the outcome. CMOc are now discussed.

CMOcs

From a realist inquiry viewpoint, a CMO configuration (CMOc) can be seen as a hypothesis that a programme outcome (O) emerges because of the action of underlying mechanisms (M), which are activated only in particular contexts (C). Pawson and Tilley (1997) see realist enquiry as enabling researchers to investigate the world from a realist perspective with a focus on the development and refinement of CMOcs. Pawson (2006) sees social programmes as providing resources (for example funding for the Lean Six Sigma education and training intervention) that activate people's reasoning: the mechanism (M). However, Pawson (2006) states that the activation of the mechanism is dependent on variables such as individual characteristics, circumstances and situations: the context (C), which leads to variation in outcomes (O). This approach to evaluating social programmes enables the theories within a programme to be made explicit, by developing clear hypotheses about how, and for whom, programmes might work, and in what context. For Pawson and Tilley (1997),

CMOcs are the foundation upon which all realist understanding is built. The very idea of configurations indicates that CMOcs are iterative and it is this iterative process that brings together and captures variations in both mechanisms and contexts to enable the researcher to understand and attempt to predict and explain outcome pattern variation.

As part of the iterative approach to the construction and refinement of CMOcs, Pawson and Tilley (1997) recommend that realist evaluators undertake a wide and varied engagement with policy makers, practitioners and participants. This deep and broad stakeholder engagement to develop and refine CMOcs requires data collection to be comprehensive and considered. Initial CMOcs were identified in chapter two and then tested through data collection and analysis (chapter four), recognising that the initial programme theory or CMOc is just the starting point for evaluation, and refinement of the CMOc through data collection, analysis and interpretation leads to the concluding findings of an evaluation (Pawson & Tilley 1997). As shown in this chapter, realist evaluation involves the development and empirical testing of CMOcs.

3.3.4 Limitations and Strengths of Realist Evaluation

Having chosen realist evaluation as the methodological approach, it is important that to identify and acknowledge its potential limitations. Byng et al. (2005) suggest that while realist evaluation is a useful research approach, its principles should not be followed dogmatically and it should allow for organic interpretation. Herepath et al. (2015) suggest that researchers tend to confuse context with intervention, with Barnes et al. (2003) claiming that there is a risk of misinterpretation of context as being purely external, and that the role of participants must not be overlooked. Herepath et al. (2015) further suggest there is a limited understanding of the nature of context and mechanism in healthcare research that can prevent a thorough analysis of their areas of intersection. Realist evaluation has become widespread in healthcare settings; however, Blamey and MacKenzie (2007) feel that it is not well matched with research requiring analysis of multi-site programmes with different interventions generating multiple outcomes, with Herepath et al. (2015) claiming that realist evaluation in healthcare risks becoming preoccupied with health outcomes as distinct from wider more systematic outcomes. Porter and O'Halloran (2011) suggest that, as it's use has

grown, realist evaluation has drifted from its roots in critical realism, with the subsequent danger of becoming technocratic. The very nature of realist evaluation and CMOcs mean that it can be both time and resource intensive for the researcher (Blamey & Mackenzie, 2007). Herepath et al. (2015) see realist evaluation as lacking the capacity to capture the complexities of intervention, context, mechanisms and outcomes.

These criticisms of realist evaluation may be off putting to a researcher looking for a suitable methodology to investigate his research question. However, they can be seen as useful warnings as to the potential hazards and pitfalls in using realist evaluation. Recognition is given that, with its iterative CMOcs, realist evaluation is a time-consuming and reiterative process, and that there may be confusion between context and mechanism. However, the choice of realist evaluation as a research methodology requires the researcher to work through expected and unexpected programme outcome patterns however they may emerge. Having an understanding of, and having agreed operational definitions for, the initial Context, Mechanism and Outcome configurations (chapter two), enabled limitations to be addressed and for the study to proceed with the categorisation of data within the configurations. This study used a systematic approach to adjudication of the programme theory, iteratively testing the refined theory with multiple stakeholders and obtaining their agreement that the CMOcs were indicative of the stratified social world in which they exist.

There are many advantages to the use of realist evaluation in health systems research. Firstly, against the 'black box' theory (Scriven, 1994; Marchal et al., 2012), realist evaluation provides a basis for the analysis of the influence of context and mechanism on outcomes (Blaise & Kegels, 2004; Greenhalgh et al., 2009; Tolson et al., 2007; Manzano-Santaella (2011); Wong et al., 2012). Rather than seeing realist evaluation as lacking the capacity to tackle complexity, it has been and continues to be used in complex healthcare situations and with complex interventions (Byng et al., 2008; Maluka et al., 2011; Pommier et al., 2010; Wand et al., 2010; Manzano-Santaella, 2011; Pawson et al., 2011). Among academic colleagues realist review has been widely used to understand such complex issues as patient and public involvement (Ní

Shé et al., 2019) and in a systematic approach to improving care for frail older patients (Ní Shé et al., 2018). These positive instances of both realist evaluation and realist review encouraged the choice of methodology. This was further supported by the availability of the RAMESES (Realist and Meta-narrative Evidence Syntheses: Evolving Standards) project (Wong et al., 2014) that offers methodological guidance in addition to publication standards and training resources. The use of the RAMESES quality standards for reviewers of realist evaluation (Wong et al, 2017) (Appendix 3.1) is detailed and discussed in chapter eight.

3.4 Conclusion

This chapter has outlined the philosophical approach to the research question *whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person-centred care and cultures*. It has discussed my own axiology, ontology and epistemological positions as well as those of critical realism, looked at the strengths and limitations of this approach, and illustrated why it was concluded that realist evaluation is a suitable choice of methodology to answer the research question. Critical realism can be seen to operate at 'mid-range' and is classified by Merton (1968) as a mid-range theory. In simple terms, mid-range theory attempts to understand interventions somewhere between their origins at a distal concept or policy level and the more proximal level of the impact of the policy on the people who are affected by it. Wong (2017) sees mid-range theory as a theory that is at the correct level of abstraction to be 'useful' and 'testable'.

Realist evaluation uses CMOcs as a particular way to express mid-range theory (Wong 2017). Newton et al. (2011) claim that realist inquiry seeks to inform the realist researcher's understanding of the relationships between context, mechanism and outcomes (CMOs) for specific interventions. This understanding facilitates progression from an initial hypothesis to the evidence-based refinement of causative factors (Pawson, 2000, Pawson et al., 2005). This methodological approach therefore is entirely suitable to address the research question. Further reasons that support the adoption of realist evaluation as the methodological approach include its focus on identifying causal factors for human behavioural change (Stame, 2007), the use of both

qualitative and quantitative research methods (Archer, 1995; Sayer, 2000), and the useful contribution of realist evaluation in healthcare research in general (Byng et al., 2008; Maluka et al., 2011; Pommier et al., 2010; Wand et al., 2010; Manzano-Santaella, 2011; Pawson et al., 2011; Ní Shé et al., 2018; Ní Shé et al., 2019) and, more recently and specifically, in analyses of Lean Six Sigma use in healthcare (Black, 2009; Mazzocato et al. 2012, 2014, 2016). All of these factors supported the understanding of the influence of Lean Six Sigma on person-centredness, person-centred care and person-centred cultures. In realist evaluation, findings are always provisional (Pawson & Tilley, 2004) 'the 'findings' of realist evaluation …pinpoint the configuration of features needed to sustain a programme' (Pawson & Tilley, 2004, p. 8).

As previously discussed, realist evaluation allows for a mixed methods approach to data collection (Pawson & Tilley, 1997) that involves the collection, analysis and interpretation of both quantitative and qualitative data in a single study (Leech & Onwuegbuzie, 2009), allowing for the study of complex interactions (Schifferdecker & Reed, 2009). However, little guidance is given on the methodological processes to be used in data collection (Gilmore et al., 2019). Therefore, whilst adhering to the principles and rigour of realist evaluation, it was considered that the use of person-centred research methodologies would be appropriate for use in data collection, as they capture the voice of the research participant (Prior et al., 2020) and include methods such as semi structured interview or focus groups which can provide a level of support while allowing participants to share their experiences. Person-centred approaches are both creative and critical (McCormack et al., 2014) with creative methods offering a different way to explore the research question with participants as they enable deeper thought on the question being discussed (Mannay, 2010, 2016 ; Kara, 2015). Kara (2015) claims that although associated with arts-based methods, there is scope for the use of creativity within traditional research methods such as oral interviews and focus groups, both of which can be used in realist evaluation, and both of which are used within this study (chapter four). Creative methods additionally create time and space for research participants to reflect on complex issues and allow time for reflection giving research participants time to think (Gauntlett, 2007). The person-centred

approach and creative methods used in this study allowed a valuable reflection space for the participants, all busy practitioners. The benefits afforded by creative methods included having the potential to develop a rapport with participants, providing them time and space to reflect more deeply on issues and to enable their thinking to be made visible (Rainford, 2020) and offered a rationale for the use of person-centred approaches within the traditional research methods aligned to the critical realist paradigm.

This chapter has highlighted critical realism and explained realist evaluation and the rationale for its use in this research. It has highlighted that realist evaluation uses programme theories to explain how an intervention is expected to work and tests these theories through the gathering, analysis and interpretation of data. The nature of the data to be gathered needs to be determined by the programme theory and the next chapter details the scope and nature of the data and the methods to be used to collect and analyse it.

Chapter 4: Research Design: Methods

4.1 Introduction

The previous chapter discussed the methodological approach underpinning this study and its initial programme theory was identified as the hypothesis that Lean Six Sigma can have a positive influence on person-centredness, person-centred care and person-centred cultures if delivered through the intervention of the UCD education and training programme (chapters one and three).

This chapter discusses the methods used in collecting and analysing data, and the design framework used to enable the testing of the programme theory. Realist evaluation enables a mixed methods approach, which was utilised as part of this study and included facilitated workshops, semi- structured realist interviews and a review of the results of Lean Six Sigma projects within participants' practice settings. Data analysis was carried out using a sequence of activities: thematic analysis of workshop outputs, a common analysis technique for qualitative research (Braun & Clarke, 2006; Bryman, 2008), and then coding and cataloguing of workshop and interview transcripts using NVivo. Integrating the data obtained from these methods was key, as it allowed argument and analysis from the different data sources to be combined (Mason 2002).

The chapter begins by first setting out the study design before moving to discuss ethical considerations and the process through which ethical approval was achieved. There is then a discussion on the recruitment of participants to the study. Methods of data collection are outlined and the analysis of the data is described and discussed. The discussion elucidates the exploration of the research question with research participants to elicit multiple perspectives and to identify emerging theories. The chapter concludes with a discussion of how the methods used facilitated answering the research question: *whether, to what extent and in what ways, Lean and Six Sigma in healthcare contribute to person- centred care and cultures*. Findings from the data collection and analysis are discussed in chapters five to seven.

4.2 Study Design

According to (Greene et al., 2005), a mixed methodological approach entails mixing methods of sampling, data collection or analysis of data. Each method used for data collection is part of a larger process with data collection seen as a series of 'interrelated activities' Creswell (2007) with the purpose of gathering information that will answer questions arising from research. As outlined in chapter three, a key reason for the use of realist evaluation in this research is its support of mixed method approaches.

In realist evaluation, the use of a broad range of data is seen as increasing the robustness of the process of theory building and testing (Wong et al., 2017). Data is required that can identify and elucidate Contexts, Mechanisms and Outcomes, and inform the relationships between them. Congruent with realist evaluation methodology (Pawson & Tilley, 1997), data collection was completed in iterative stages using a combination of data collection methods. The study design comprised an initial realist review of literature to identify initial Context, Mechanism, Outcome Configurations (CMOcs) (chapter 2). Three multi-faceted and complex CMOcs were identified and a decision made to focus on the CMOc, 'Lean Six Sigma and Staff', and a rationale offered to support this choice. This particular CMOc identified five further potential contexts or contextual factors, seven mechanisms and six outcomes that, in line with realist evaluation methodology, required further analysis and iterative adjudications. To facilitate this, further data collection was carried out in the following sequence:

1. A series of facilitated workshops with graduates of the UCD Lean Six Sigma programme (n=20) to adjudicate the CMOc, Lean Six Sigma and Staff. The person-centred principles of Collaborative, Inclusive and Participative (CIP) ways of working (Manley et al., 2014; Dewing et al, 2015) underpinned the approach to these workshops to gather participants' views and experiences as Lean Six Sigma practitioners. A range of creative approaches were used to achieve these collaborative and inclusive ways of working including the use of

pictures and creative constructs (Coats et al., 2006) and other means such as the use of painting and collage (McCormack et al, 2006; Foster, 2007).These approaches facilitated participant feedback and adjudication of the programme theory, adjudication being the interrogation of underlying causal processes (Pawson, 2013), and further facilitated thematic analysis. The ultimate purpose of data analysis through adjudication is to identify whether participants 'inspire/validate/falsify/ modify' (Pawson, 1996, p. 295) the programme theory.

2. Individual interviews with workshop participants (n=20) to further explore the themes that were developed in their first workshop and to refine the initial programme theory through individual adjudication of the CMOc. These interviews were facilitated using semi-structured realist interviews (Manzano, 2016).
3. A second series of facilitated workshops with graduates of the UCD Lean Six Sigma programme (n=20) to arrive at a final adjudication of the CMOc as refined in workshop one and further refined in the individual interviews. These workshops again used collaborative, inclusive and participatory principles to facilitate participant feedback and enable thematic analysis. In these workshops, participants located the adjudicated CMOc within the synergies and divergences identified between Lean Six Sigma, person-centred care and person-centred cultures in chapter two (figure 2.18).

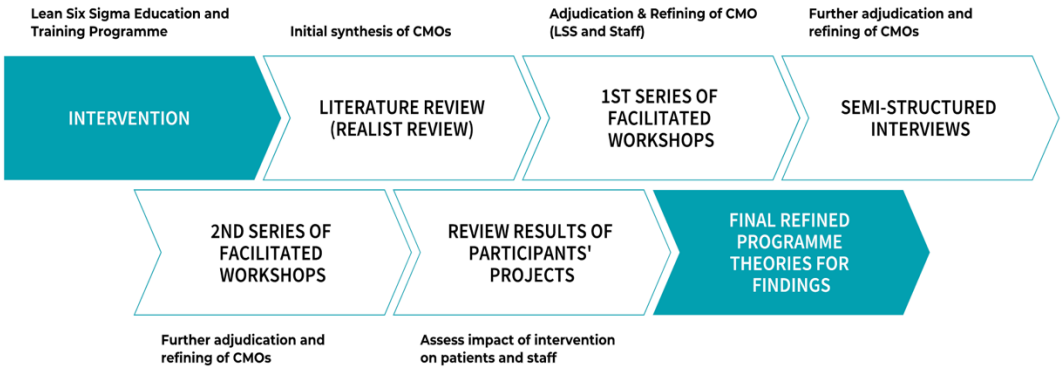
Iterative analysis of the workshop and interview data centred on participant's perceptions and interpretation of the CMOc, Lean Six Sigma and Staff, to develop refined configurations of the initial CMOc. Data collection took place over a seven-month period between January and July 2019.

4. The results of participants' Lean Six Sigma projects, already in the public domain, provided supporting evidence for the outcomes of their Lean Six Sigma work in their area of practice and provided evidence of improved patient and staff experiences, and patient outcomes. Results were presented in scientific poster presentations (Appendix 4.1) and peer-reviewed publications

(O' Hora et al., 2015; O'Toole et al.2016; Kieran et al., 2016; Hayden et al., 2016; Feeney et al., 2016; Kieran et al., 2017; Brown et al., 2019; Creed et al., 2019; Davies et al.,2019; Hynes et al., 2019; McGrath et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019). This review took place in July and August 2019.

This approach, summarised in figure 4.1, is congruent with the use of realist evaluation as the methodology, with the study completed in iterative stages (Pawson & Tilley 1997) using a combination of data collection methods.

Figure 4.1: Process for Data Collection



The use of person-centred principles to guide data collection provided time for participants to reflect on the presented CMOc and to consider whether and to what extent their own ways of working and their experiences as Lean Six Sigma practitioners were reflected in and by it. Use of the principles also created a safe space (see section 4.4.1) for participants to examine their Lean Six Sigma practice. The collaborative, inclusive and participative work was facilitated by the shared purpose of participants to adjudicate the programme theory.

> Shared purpose results when a group of individuals aligns their belief systems or values with a common challenge, vision or goal
>
> (Finney, 2013, p 5).

Shared purpose has been shown to unify diverse groups in collaborative activity, enabling participants to work together creatively in the same direction (Manley et al., 2014).

In previous chapters, the lack of research on the influence of Lean Six Sigma on person-centredness, person-centred care and person-centred cultures was identified. Although realist evaluation has been used in the evaluation of Lean and Six Sigma programmes in healthcare internationally, there is little understanding of whether, to what extent and how Lean Six Sigma education and training programmes influence healthcare staff and person-centredness when used in healthcare practice. The design and methods of this study seek to reveal this influence within the complexities of a busy healthcare environment. In developing the CMOc to test with study participants, there was continual return to the fundamental realist question of 'what worked for whom in what circumstances'? The key role of participants within this study meant that the ethical robustness of this study was a major consideration. Ethical considerations are now discussed.

4.3 Ethical Considerations

4.3.1 Ethical Approval

Ethical considerations were guided by the requirements of the Mater Misericordiae University Hospital which stipulates that ethical approval may only be given following review by a nominated Ethics Committee to ensure that that the study complies with the Declaration of Helsinki, Irish law and European Union (EU) law. This ensured that the design, conduct and governance of this study were guided by the ethical principles of dignity, autonomy, beneficence, and justice (Beauchamp & Childress, 2001). Dignity and autonomy acknowledge the person as an individual and recognise the requirement that research participants give informed consent to participate in the research and have the ability to withdraw from the study (see section 4.3.3). The principle of beneficence required me to protect participants by seeking to maximise anticipated benefits, such as their contribution to this research, and minimise possible

harms, such as loss of dignity, privacy or respect. This required me to reduce any risk of harm to participants by changing the design of the study if necessary. This was facilitated by reflecting on the initial data collection plan with my supervision team and discussing what would work for both myself and participants in the contexts and circumstances of the study site. The final principle of justice (Beauchamp & Childress, 2001) requires that the researcher treats participants fairly and as equals.

There was a constant awareness that participants would be invited to provide their opinion and discuss aspects of their Lean Six Sigma practice in their specific practice areas and more widely at the study site, and some of this might be sensitive for them. I therefore drew on previous experience as a facilitator of person-centred cultures to model person-centred principles in working with participants. As previously discussed, person-centred principles informed all interactions with participants, treating them in the manner I would expect to be treated, with due regard for their privacy, dignity and wishes as a willing volunteer. I found that asking people to engage in creative thinking and group discussions enabled true experiences to shine through in a way they might not have if I had only been asking direct questions of people. Following submission of the required documentation to the committee (Appendix 4.2, Application Document Checklist), the researcher was invited to discuss this study with the committee. Ethical approval was granted (Appendix 4.3) on 24th October 2018.

4.3.2 Researcher Reflexivity

Holmes (2020) states that positionality acknowledges and recognises the researcher as part of the social world they are researching and that this world has already been interpreted by existing social actors. This is congruent with realist evaluation, with Pawson and Tilley (1997) explaining that, because social reality is stratified and different social actors will perceive their own situations and circumstances differently, the researcher aims to understand the social world as perceived and experienced by these social actors. Reflexivity informs positionality. It requires the researcher to be explicitly self-consciousness and to undertake self-assessment about their views and positions and how these may have already or might influence the design, execution, and interpretation of the research data findings (Greenbank, 2003, May & Perry, 2017).

Throughout the research I remained cognisant of my role as both the researcher and as a lecturer on the Lean Six Sigma education and training programme (the intervention), a research insider, and that remained a concern for me and again was a continuous topic of discussion with my supervision team. The use of reflexivity is important for this study as relates to methodology, person-centredness and organisational change:

- Methodologically the use of reflexivity is congruent with realist evaluation, utilising multiple data sources and methods in a pragmatic and reflexive manner to build a picture of the case, which calls for making sense of various data sets to develop coherent and plausible accounts of the phenomena under investigation (Greenhalgh et al., 2009; Rycroft-Malone et al., 2010)
- From a person-centred perspective, Cardiff et al. (2018) indicate that reflexivity is a skill that person-centred leaders need to nurture.
- In relation to organisational change and development (such as the intervention of the Lean Six Sigma education and training programme) reflective practice is highlighted as being a central part of the change process (Fielding et al., 2005).

Reflection and reflexivity are essential for responsible and ethical practice, with reflection being seen as a state of mind, an ongoing constituent of practice rather than a technique (Bolton, 2014), and reflexivity as a continuous and integral part of the research process (Williamson et al., 2012). Due to the proximity of researchers to participants, researchers are required to engage reflexivity by acknowledging and addressing personal biases (Koch & Harrington, 1998), and their subjectivity, therefore demonstrating credibility by acknowledging the role of reflexivity (Bradbury and Reason, 2005). Waterman et al., (2001) suggest that reflection is a vital component in the research cycle, in tandem with reflexivity and an account of how it is employed in any project, particularly in reference to service developments (such as the Lean Six Sigma work ongoing in this study) and the data gathered in the study process needs to be demonstrated. This researcher reflexivity enables engagement in critical self-reflection about any personal biases, preferences and preconceptions (Polit and Beck, 2008) with theorists encouraging researchers to lay out their prejudices in a reflexive process (Selvam & Collicutt, 2013). Flexible reflexivity is enabled by reflection and evaluation as the cyclical

process promotes the search for alternative ways of behaving, frames of reference or monitoring of outcomes (Ungar et al., 2015). Hammersley and Atkinson (2007) suggest that rather than trying to eliminate the effects of the researcher, reflexive researchers actually try to understand them. Throughout all cyclical stages of the research process I reflected continuously on my interactions with participants and the interpersonal relationships involved, and maintained an awareness of the question of power and having a relationship with all participants based on trust, respect and reciprocity (Barton, 2005). Reflexivity was managed at each stage of the study and made use of the following methods:

- Reflection after each stage of the process facilitated by Rolfe et al.'s (2001) 'What, So What, Now What' model.
- Consideration and reflection on my own listening skills, facilitated by Dewing et al's. (2014) process evaluation record, which was particularly useful at the individual interview stage.
- Use of a personal research journal capturing my reflection on each stage of the process.
- Reflection and feedback with the community of practice for doctoral students (SICOP) at Queen Margaret University following the interviews and before the final series of workshops
- Personal critical reflection using creative methods at all stages of the process.

The above methods are discussed further throughout the rest of this chapter, and they indicate the amount of intellectual and mental input required for reflection and reflexivity (Raelin, 2009). However, without this essential intellectual and mental input and researcher reflexivity, the research may not be conducted ethically (Holmes, 2020). Therefore it is essential to 'pay attention to attention to positionality, reflexivity, the production of knowledge... to undertake ethical research' (Sultana, 2007, p.380). The clear message here is that without reflexivity on the part of the researcher, their research may not be conducted ethically. Reflexivity and clarification of the researchers positionality may, therefore, be seen as an essential part of the research process, and of this study.

4.3.3 Recruiting Participants

Purposeful sampling is a technique widely used in qualitative research for the identification and selection of information-rich research cases and the most effective use of limited resources (Patton, 2002). It involves identifying and selecting individuals or groups of individuals that are especially knowledgeable about or have experience of the phenomenon of interest (Cresswell & Plano Clark, 2011); these are 'key informants'. In addition to knowledge and experience, Bernard (2002) and Spradley (1979) note the importance of availability and willingness to participate, and the ability to communicate experiences and opinions in an articulate, expressive, and reflective manner. According to Greenwood and Levin (2007) there are two types of credible knowledge: internal and external. Internal credibility refers to the ability of the process to be authentic to those who participated in it, while external credibility refers to how uninformed others external to the process are convinced by its authenticity (Greenwood & Levin, 2007). Authentic collaboration is enhanced by a purposeful sampling methodology, which enhances active participation in the research process enabling the purposeful exploration of the extensive knowledge of participants in the process (Beringer and Fletcher, 2011). This is synergistic with person-centred CIP principles (Manley et al, 2014; Dewing et al., 2015) which were used throughout this process.

The sample size was purposive (n= 20), derived from Mater Hospital staff from a range of disciplines and functions, all graduates of the Mater Lean Academy/UCD Lean Six Sigma education and training programme, having graduated between 2014 and 2017, and currently working in the hospital (n=97). This sample constituted 20% of the population of Lean Six Sigma graduates in the hospital and was a feasible number of participants to work with. Graduates of the intervention programme were chosen in line with realist evaluation principles, with Pawson and Tilley (1997) highlighting that they will probably have experienced both the successes and failures of the programme intervention and will be best placed to advise on outcomes.

Participants were selected by purposive sampling according to the following criteria:

Inclusion criteria

- Graduate of Mater Lean Academy/UCD programme (2014-2017)
- Current member of staff within the Mater hospital

Exclusion criteria

- Graduates of Mater Lean Academy/UCD programme who no longer work in the hospital (as their Lean practice does not relate to the Mater hospital)
- Non-Mater hospital staff who undertook the programme
- Graduates currently involved in another research project (so as not to detract from their work on that project or place additional demands on their time).

The purposive sample was designed to enable data generation on the study's programme theory, draw clear inferences and credible explanations from the data that was generated and to be as efficient as practical (Kemper et al, 2003).The Mater Hospital Institutional Review Board had recommended that the selection of participants should be unbiased and by an independent person other than the researcher. This recognises the issues of power and relationship (Barton, 2005) and of proximity to participants (Williamson et al., 2012) which was alluded to in section 4.3.1, and seeks to minimise any potential selection bias. Therefore, a member of the administrative staff entered the names of all staff currently working within the hospital who met the inclusion criteria (n=97) into a random name generator and thirty staff were randomly selected. The rationale for choosing thirty was that not all staff might respond or wish to participate. The initial twenty names drawn were included in the initial invitation to participate in the research.

4.3.4 Invitation and Informed Consent

Letters of invitation and a participant information leaflet (Appendix 4.4) were sent to the first twenty names drawn that met the inclusion criteria with a plain language summary of the PhD and study (the leaflet explained why they had been invited to participate in the research). The letter advised recipients that if, having read the participant information leaflet, considered the research and decided they would like to participate in the study, they should then complete and return the consent form (Appendix 4.5). Participants were informed that they could leave the study at any point

prior to the data being anonymised and it was made clear what would happen to the data gathered on completion of the research (Kirkby et al., 2001). The purpose of consent forms is to allow study participants to make a voluntary informed decision about whether or not to participate in a study (Peled & Leichtentritt, 2002). The consent form also stated that participants could withdraw from the study at any stage but clarified that once data had been anonymised it would not be possible to withdraw it from the study. This was indicated because once data are anonymised and amalgamated with other participants' data into CMOcs, they could not then be excluded. Ultimately, no participants withdrew their consent.

The initial response rate was 70% or fourteen participants all of whom agreed to participate without requiring any clarifications. After the ethically-approved period of two weeks for staff to read the participant information leaflet and ask any clarifying questions about the study, an email reminder was sent to the six staff (30%) that had not responded. Following this, a further four staff agreed to participate. At this point an invitation was issued to the next ten names drawn on the randomly-generated list and the cycle of two weeks repeated. A further two staff responded that they would like to participate. Having reviewed the consent forms of the twenty participants, a decision was made to seek no further participants, as this equated to 20% (n=97) of the overall population of individuals meeting the inclusion criteria. It is important to acknowledge that the process of engaging participants was undertaken within the context of high volumes of work and high patient attendances at the hospital. Their participation was and is valued and appreciated.

4.4 Data Collection

As discussed in detail in the previous chapter, in realist evaluation the aim of data collection is to enable a focus on CMOcs (Pawson & Tilley, 1997). The intent was to elicit participants' understanding of the CMOc, 'Lean Six Sigma and Staff', and their experiences in their practice areas as graduates of the Lean Six Sigma education and training programme. Each collection method used provided one piece of a bigger picture and data collection was not a series of discrete and separate tasks but was rather 'a series of interrelated activities aimed at gathering good information to answer

emerging research questions' (Cresswell, 2007 p. 118).

Pawson and Tilley (1997) suggest that the process that occurs throughout the data collection process (figure 4.1) entails a movement from the empirical data of the realist review to the abstraction of ideas. As indicated in figure 4.1, in addition to the realist review, data collection had four phases: an initial series of workshops, individual semi-structured interviews, a second series of workshops and a review of results of participants' Lean Six Sigma projects. Through the four phases, a mixed methods approach was therefore employed.

Realist evaluation does not employ particular data collection methods, but a mixture of qualitative and quantitative methods is encouraged (Pawson et al., 2005). Realist evaluation values mixed method approaches and suggests that data types should be selected for their potential contribution to the research. Cresswell (2003) suggests that to limit data collection to either qualitative or quantitative approaches does not meet the standards set within the human and social sciences. Currently, research practice is often not purely quantitative or qualitative but located on a continuum between the two, using mixed methods (Creswell 2003). Mixed methods recognise that both quantitative and qualitative research approaches are important and useful, and Bergman (2008) recommends a combination of at least one quantitative and one qualitative component in a single research study. Johnson and Onwuegbuzie (2004) state that mixed methods research allows broader and more complete research questions to be answered. They further suggest that the use of mixed methods produces more complete knowledge that is necessary to inform both theory and practice. Having discussed the realist review and findings (chapter two), each of the four data collection strands are discussed in more detail.

4.4.1 Preparing for the Workshops

During this PhD journey, I developed an appreciation of new ways of working that are conducive to person-centredness. As discussed in chapter one, I undertook a year-long accredited programme with the Health Service Executive and Queen Margaret University (QMU) to become a facilitator of person-centred cultures, which deepened

my understanding and use of person-centred approaches to care. It was important to ensure that data collection and analysis were underpinned by person-centred principles that have been shown to be an effective and acceptable way of capturing the experiences of participants (Prior et. al, 2020) and of facilitating authentic collaboration (Beringer and Fletcher, 2011).

In their practice development framework, Manley et al. (2011) suggest ten core values for an effective workplace culture (figure 4.2), and I have particularly learned from their work on how to engage and work with others to develop effective workplace cultures. I wanted the workshops to facilitate the flow of communication, with participants free to ask challenging questions of each other and me, but in a supportive way. The Collaborative, Inclusive and Participatory (CIP) principles (Manley et al., 2014; Dewing et al., 2015) were key to my understanding of the way the workshop would be structured. This preparation also was beneficial for the interviews.

Figure 4.2: Ten Core values for Effective Workplace Culture

Source: Taken from Manley et al. (2011, p. 12)

I re-read my thesis to date, reviewed the CMOc (Lean Six Sigma and Staff) and its components that I wanted participants to discuss and adjudicate, and discussed my approach to the workshop/s with my supervision team. We agreed that, in the interest of making the workshops creative and safe spaces, they should comprise small groups, to allow more focus on what individuals said, and that I should seek the assistance of

a colleague to take notes. Additionally, as the consent allowed for recording, I planned to record both the workshops and the interviews to generate both notes and transcripts. We discussed how the workshops would be organised (further details below) and agreed on a structure that would facilitate a person-centred culture that supported the exchanging of experiences and ideas in a safe and supportive manner while providing opportunities for dissenting views to be of equal importance .

To prepare a realistic schedule and consistent with the consent form, the first facilitated workshop invitations were issued to all who had agreed to participate. The invitations were sent using Doodle Poll to allow for the participants to choose dates which would best suit the work demands of their practice area and their own schedules. All workshop sessions were scheduled for lunchtimes and, following discussion with my supervision team, it was envisaged that two hours would be required to allow for a productive but relaxed workshop. When the Doodle polls returned it was clear that to facilitate all those willing to participate and to enable them to participate for two hours I would have to hold three workshops of eight, seven and five participants, respectively (table 4.1).

Table 4.1: Participants in First Series of Workshops

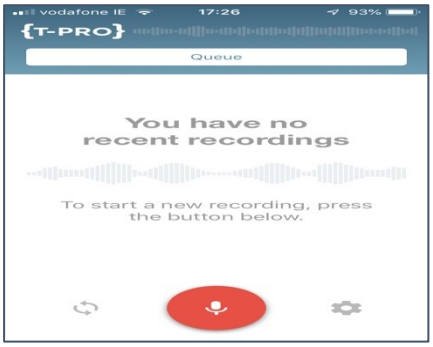
Workshop 1.1	Workshop 1.2	Workshop 1.3
Data Manager	**Administration Team Manager**	**Pharmacist**
Operations Manager x 2	**Clinical Nurse Specialist**	**Speech & Language Therapist**
Assistant Director of Nursing	**Practice Development Nurse**	**Data Coordination Lead**
Clinical Trials Manager	**Data Coordinator**	**Administration Team Manager**
Senior Medical Scientist	**Physiotherapist**	**Assistant Director of Nursing**
Discharge Coordinator	**Project Manager**	
Service Improvement Lead	**Radiology Manager**	

A meeting room was booked within the hospital that could comfortably accommodate up to 25 people and had natural daylight and ventilation, air-conditioning and heating options. It was also well removed from the clinical area to provide participants with a safe and comfortable space to work. Tables were available to work with a range of

materials and additional tables from which to enjoy lunch. There was plenty of wall space for to display participants' work. Flip charts, coloured markers and materials such as stickers, glues, paints, crayons and picture cards were provided by the Lean Academy. Catering was also provided. A smaller office away from the main clinical core of the hospital was identified for the subsequent individual interviews.

The Hospital uses a system called T-PRO for its clinicians to securely record sensitive medical data. It operates via an app on a phone (figure 4.3) that the clinician can use to record their dictation. Once they have reviewed the recording, they press send and it automatically goes to the appropriate medical secretary for transcription. This ensures a secure pathway for the transfer of sensitive patient information. I met with the Deputy Medical Records Manager and explained the research and she agreed to assign an account to me for the duration of this study. A medical secretary in the hospital agreed to transcribe the workshops and interviews, with funding for this supplied by the Dean of the UCD School of Nursing, Midwifery and Health Systems. The medical secretary had a specific account created that linked to mine. This gave me the ability to record workshops and interviews and, following an initial review, to send them directly to the secretary for transcription. This system is used for confidential patient data on a daily basis so I could be sure of the confidentiality and security of the participants' data, and the information was safely encrypted. I took time to discuss with the medical secretary the ethical considerations and guarantees I had given to participants and secured her agreement to work in this way. Participants also agreed to the use of a camera to record shots of the workshop and materials used as set out in the consent form. The scribe used an iPhone 7 camera to capture a photographic record of the workshops. These photos were then emailed from the iPhone directly to the medical secretaries T-Pro account.

Figure 4.3: T-PRO app



4.4.2 Workshops (Series One)

The first series of three workshops were scheduled via Doodle Poll with a gap of a week between each to enable me to reflect on each individual workshop on what worked or what didn't work well, what key issues were emerging, my line of enquiries to pay attention to in future workshops and how I could build on the knowledge generation and my facilitation roles within that from each. A buffet lunch was available during the workshops to help create a relaxed atmosphere, and participants were encouraged to avail of tea, coffee and water throughout. I thanked participants for their attendance and gave an overview of the research. I also offered participants the chance to ask any new or further clarifying questions. Before commencing, and to highlight the ways we would work, I reminded participants of the collaborative, inclusive and participatory (CIP) principles that are integrated into the UCD Lean Six Sigma programme and the high-challenge, high-support approach of this programme with which they were familiar. Participants were reassured that the study was being conducted for scholarly research purposes only, that under no circumstances would their names be revealed, and that their responses and data would be coded and securely held. Additionally, I assured participants that there was no such concept as a 'right answer' and that the aim of the workshop was to discover their unique experiences and perspectives as Lean Six Sigma practitioners in their practice areas. This was important, as it acknowledged and addressed the question of power and helped to establish and maintain a relationship with all participants based on trust, respect and

reciprocity (Barton, 2005).

To facilitate ice breaking and to enable the participants to discuss their Lean journeys to date in a relaxed manner, I asked each participant to bring an artefact to their workshop (figure 4.4), which signified their current thoughts on their role as a Lean Six Sigma graduate within their practice area. Artefacts have been found to be useful in qualitative data collection as they can assist in eliciting information that may not have been uncovered with traditional question and answer methods (Bahn & Barratt-Pugh, 2011). Artefact use can include (but is not limited to) pictures (Loeffler, 2005; Stanczak, 2007), poetry (Szto, Furman and Langer, 2005), painting and collage (Foster, 2007). The artefacts proved useful for introductions and enabled each participant to speak about their own experience and use of Lean Six Sigma within their practice areas.

Figure 4.4: Participants' Artefacts

Following the introductions and discussion of their artefacts, I gave the participants an overview of the nature of CMOcs, using healthcare examples to facilitate their understanding and explained that we were looking specifically at Lean Six Sigma and outcomes associated with staff. This is congruent with the teaching–learning dynamic in realist evaluation (Pawson & Tilley, 2004). It also made clear that the purpose of

the workshop was for participants to review and adjudicate on a CMOc derived from the literature from their perspectives as practitioners in diverse areas and to consider the staff-related factors that, if present, facilitated Lean Six Sigma use in healthcare organisations. Coloured display boards (figure 4.5) were hung on the walls of the room, each containing the specific Contexts, Mechanisms and Outcomes identified in the CMOc 'Lean Six Sigma and Staff ' in the realist review (figure 2.21).

Figure 4.5: CMOc Boards

The Context, Mechanisms and Outcomes derived from the literature were shared with the participants using these display boards and were key to the review of the CMOc by participants throughout the workshops. The display boards were uncovered incrementally during the workshop (table 4.2) so that participants were first generating their own CMOc based on their experiences.

Table 4.2: Cycle for Participant Review of the CMOc (Workshop Series One)

CYCLE	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
1.CONTEXT	15 minute individual reflection	Individual feedback to group	Group discussion	Clarifying questions	Review of Context board	Identifying any Context Synergy and any new Contexts	5 minute Break
2.MECHANISM	15 minute individual reflection	Individual feedback to group	Group discussion	Clarifying questions	Review of Mechanism board	Identifying any Mechanism Synergy and any new Mechanisms	5 minute break
3.OUTCOME	15 minute individual reflection	Individual feedback to group	Group discussion	Clarifying questions	Review of Outcome board	Identifying any Context synergy and any new Contexts	Sum up

This approach allowed any synergy or divergence with the CMOc derived from the literature as well as new information and emerging theories (i.e., new Contexts, Mechanisms and Outcomes) to be identified and recorded. The aim was to elicit participants' views, experiences and beliefs about the intervention (the Lean Six Sigma programme) and compare these with the relevant to the CMOc being adjudicated (Lean Six Sigma and Staff) in order to enable them to contribute to theory-testing (Pawson & Tilley, 1997). Individual blank workbooks each containing a section for Context, Mechanism and Outcome were provided for each participant (figure 4.6).

Figure 4.6: CMO Workbooks

The workbooks were colour coded to match the CMOc boards for ease of identification of specific Contexts, Mechanisms and Outcomes. There then followed a structured cycle (table 4.2) in which, individually and as a group, participants were encouraged to take fifteen minutes to write their own thoughts on what Contexts, Mechanisms and Outcomes were relevant to them in their daily practice as Lean practitioners, building on their personal artefacts. I remained on hand to offer clarification as required. Relaxing music was played with the agreement of all present.

Following this, participants were invited to feedback to the group their thoughts on the Contexts, Mechanisms and Outcomes relevant to their practice settings and experience as Lean Six Sigma practitioners. Time was allowed for clarifying questions arising from the discussion and then the relevant Context, Mechanism or Outcome board was revealed to the participants. Participants were asked to identify where their own experiences had reflected the findings from the literature and to mark on the CMO boards on the wall where they had identified new CMOs and to write any additional thoughts or comments. Between each cycle there was a short comfort break before a final sum up.

Through these workshops, the data collected comprised:

1. Artefact photographs
2. Scribed notes
3. Marked up CMOc boards
4. CMOc workbooks
5. Photographic records of the workshops
6. Audio-recordings for transcription

The facilitated workshops allowed data to be collected using person-centred approaches while meeting the requirements of realist data collection, which according to Pawson and Tilley (1997) is concerned with

> asking questions about the reasoning and resources of those involved in

> the initiative, the social and cultural conditions necessary to sustain change, and the extent to which one behavioural regularity is exchanged for another.
> (Pawson & Tilley, 1997) p. 154)

Workshops have been shown to be an effective method of refining theory using realist evaluation (Rushmeer et al., 2014) and this first series of workshops enabled what Pawson and Tilley (1997) term pattern identification with participants in a 'theory-testing role'. Rushmeer et al. (2014), in evaluating a 'knowledge to action' programme, noted that workshops can enable a 'two-way process where knowledge, evidence, opinions and experiences of 'what works' are shared and discussed by stakeholders' (Rushmeer et al., 2014, p. 553). The workshops enabled this two-way process for me as a researcher, enabling the CMOc derived from the realist review to be adjudicated by the workshop participants and the programme theory to be refined.

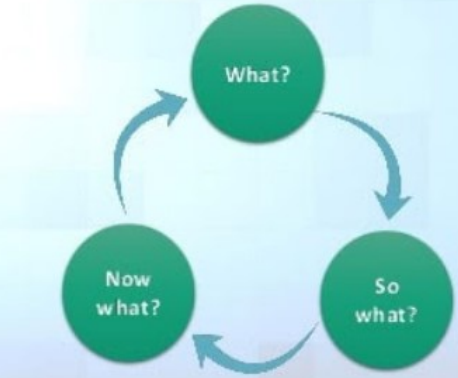
At the end of each workshop, a small 'debriefing' exercise was carried out using Evoke© cards, cards with wording on one side and a picture on the other, that can be used by individuals or teams to evoke a range of emotions, memories and thoughts. Each participant chose a card to feedback on how they felt after the workshop. This was consistent with the duty of care held by the researcher to be mindful of participants' feelings. Participants were talked through the next steps of the research in line with the letter of invitation and information leaflet (Appendix 4.4). They were advised that once the first series of workshops were complete that the audio, pictorial, workbooks, artefacts and notes from each workshop would be reviewed, analysed thematically and coded. When this sequence was complete, Doodle invitations would be sent to all participants inviting them to an individual interview, during which we would review the data from the workshops and work on further refining the CMOc. I advised all participants to contact me if they had any queries and I also asked anyone who had any concerns or required any clarification to contact me and I would arrange to meet with them individually.

Following each of the workshops comprised the first series, I took time to reflect on

the workshop, my own feelings and my understanding of how I had facilitated it. I made use of a reflective tool from the person-centred cultures facilitators' course, Rolfe et al.'s (2001) 'What, So What, Now What' model (Figure 4.7). The tool highlights areas for learning and development. It was particularly useful for me to reflect between each workshop so that the learning and programme theory insights could feed forward to subsequent data collection.

Figure 4.7: Framework on Reflective Practice

Stage	Details
'What?'	Describe the situation; achievements, consequences, responses, feelings, and problems
'So what?'	Discuss what has been learnt; learning about self, relationships, models, attitudes, cultures, actions, thoughts, understanding, and improvements
'Now what?'	Identify what needs to be done in order to improve future outcomes, and develop learning.



Source: Adapted from Rolfe et al. (2001)

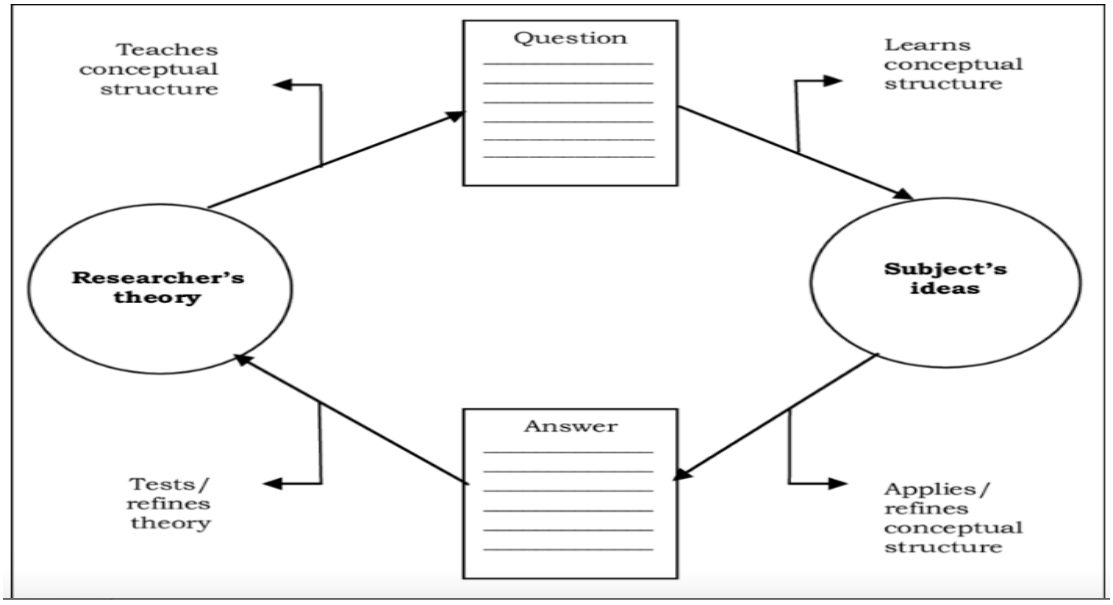
4.4.3 Individual Interviews

Following the first three workshops, the next adjudication of the CMOc took place through individual interviews (n=20). The interview is a common method of data collection in qualitative research (Mason, 2002). The use of semi-structured interviews within a realist structure (Pawson & Tilley, 1997) facilitated an interview format that allowed pre-determined topics to be covered; however, it also afforded the flexibility to discuss individual participant's experiences in more detail.

The realist interview technique comprises a semi-structured interview process that has two aspects specific to realist evaluation: a 'teacher learner function' and a 'conceptual refinement process'. The interview starts with the researcher 'teaching' the participant 'the particular programme theory under test' (Pawson & Tilley, 2004) in this case that

Lean Six Sigma introduced through the intervention of the UCD education and training programme can contribute to person-centredness, person-centred care and person-centred cultures (chapter 1). Having learned and understood the theory being tested, the participant is then reciprocally able to teach the researcher about elements of the programme theory from their own point of view and in an informed way (Pawson & Tilley, 2004). Within realist interviews there is explicit discussion of the programme theory with the participants, giving them the opportunity to confirm, refute or refine it (Flynn et al., 2019). Mukumbang et al. (2020), in a review of the realist interviewing approach suggest that it underpins and maintains theoretical awareness throughout the evaluation process. Manzano (2016), in her discussion of interviewing in realist evaluation, emphasises that the teacher and learner are fluid roles during the process of discussion of the programme theory. The conceptual refinement component enables participants in the course of the interview to discuss, explain and articulate their individual thinking about the programme theory and to use their experience to adjudicate and refine the CMOc. This is a collaborative form of theory refinement (figure 4.8) in which the interview is guided by the theories the researcher is aiming to refine (Pawson & Sridharan, 2010; Pawson and Tilley, 1997; Manzano, 2016).

Figure 4.8: Realist Interview Structure



Source: Taken from Pawson and Tilley (1997, p.165)

The technique allows both interviewer and participant to refine further the previously identified CMOc (synthesised from the literature and adjudicated in the first series of workshops). It also allows the Contexts, Mechanisms and Outcomes most relevant to the participant to be discussed in more detail. The theory-driven realist interview can inspire participants and enable them to validate, refute or modify the CMOc in light of their own experience (Pawson, 1996). A key requirement of realist interviews is that the researcher has established their programme theory and has some understanding of the natural setting where the theories are at work (Wong et al., 2017). The initial programme theory was that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD education and training programme. This was explored through the realist review (chapter 2) before being adjudicated by participants during the first series of workshops.

As with the workshops, preparation of the environment, the materials and myself was important. In relation to the environment, I used an office in a quiet location of the hospital. This afforded privacy, a space away from the busy clinical core of the hospital, and a relaxed atmosphere. The office was well ventilated, had natural daylight and was free from interruption. Lunch and other refreshments were provided. T-PRO was again used to record the interviews.

The refined CMOc arising from the first workshops was formulated into a colour-coded worksheet (Figure 4.9) The colour coding continued the coding sequence used in the workshop workbooks and CMOc boards with which the participants were familiar and served as an introduction to the refined CMOc arising from the workshops.

Figure 4.9: CMOc Worksheets

Invitations to interview were again sent using Doodle Poll to allow the participants to choose dates that would best suit their work and other commitments. All interviews were scheduled for lunchtime or other times that best suited the participants and as indicated in the Participant Information Leaflet, they lasted no longer than forty minutes. Participants were also invited to bring their artefact from the first workshop with them for reference.

Interview questions were developed to support the realist approach of teacher-learner, allowing further refinement of ideas about how the programme works, drawing on participants' experience and expertise of using of Lean Six Sigma in their practice areas (Manzano, 2016). The questions were developed with reference to expert guidance on realist interviews (Manzano, 2016; Wong et al., 2017; Westhorp & Manzano, 2017) and were discussed, reviewed and agreed with my supervision team. The interview format reflected the CMOc structure with questions developed under three themes (Appendix 4.6):

1. Context: what conditions are required for a Lean Six Sigma measure to trigger mechanisms?
2. Mechanism: what is it about an intervention that may lead to it having a particular outcome? How does the intervention work?

3. Outcome/outcome patterns: What are the practical effects in a given context?

Twenty participants were interviewed. The interviews used the colour-coded worksheets (Figure 4.9) for reference and explored their experiences of using Lean Six Sigma in their practice. During the interviews I asked additional questions where relevant. Participants were encouraged to provide their thoughts and feelings about contextual factors, and about the mechanisms that enable or hinder the Lean Six Sigma education and training programme in achieving outcomes. The time spent discussing the CMOc in each interview varied according to individual participant's experience. Average interview time was 37.58 minutes, with the longest being 41.41 minutes and the shortest being 22.18 minutes.

Through the interviews, the data collected were as follows:

1. The artefact revisited
2. Scribed notes
3. CMO worksheets marked-up by participants
4. Audio-recordings for transcription

The realist interviews further refined the CMOc synthesised from the literature and refined in first series of workshops. Throughout all stages of the data collection, I remained aware that part of the role of the realist researcher is to look for emergent CMOcs (Pawson, 2013) not previously generated (Manzano, 2016). Interviews are useful for data collection as they facilitate exploration of the thoughts, opinions and experiences of participants (Barribal & White, 1994); these are valuable and essential for refinement of the CMOc. At the end of each interview, I debriefed each participant, asking them how they felt, answering any queries they had and inviting them to have another refreshment before they left. I advised participants that, once all interviews were complete, the worksheets and recordings from each interview would be reviewed, analysed thematically and coded. They would then be invited to a final facilitated workshop during which we would review the data from the interviews and work on further refining the CMOc. I advised that, like the first workshop, these workshops would also involve person-centred approaches using creative materials and based on

the CIP principles. I advised all participants to contact me if they had any queries or concerns or required any clarification and I would arrange to meet them individually.

After each interview, I again used Rolfe et al.'s (2001) reflective tool for my own learning and to enable me to catalogue first impressions from the interview and how they related to what was already know, as represented in the CMOc. I also used an evaluation sheet, which enabled me to reflect on my own listening skills (Appendix 4.7). I had encountered this as part of my experience as a facilitator of person-centred cultures (Dewing et al., 2014). This period of reflection allowed me to refine my own attention to, and understanding of, participants' experience and was effectively the first stage of analysis.

Further reflection was enabled with my doctoral student colleagues at QMU, Edinburgh. As a student at QMU, I am a member of a thriving community of practice for doctoral students (SICOP), all of whom are studying different aspects of person-centredness (McCormack & Dewing, 2019; Sanders et al., 2020). The ethos of SICOP includes the co-creation of an accepting and safe space with colleagues we can trust, and where creativity can flourish (Lynch & Frost, 2015; Sanders et al., 2020). As part of the sharing of our research journeys, I discussed my stage of data collection and that I was moving toward a second series of workshops. With one of my doctoral supervisors and thirteen other doctoral students in the room, I suggested ways in which I planned to make the data collection for the second series of workshops more creative and fun for the participants, while still exploring the CMOcs and testing the programme theory further. I invited my colleagues to silently share through Post-its© their thoughts on what I had presented and, importantly, which of my suggested approaches to data collection they might take (figure 4.10). I had considered that participants might:

1. revisit the artefacts from the first series of workshops and individual interviews
2. work in teams
3. make something creative to reflect their understanding of the CMOc
4. rank their experiences to adjudicate CMOc using Eurovision© style voting

5. use a combination of points 1-4

My fellow doctoral students suggested option 5, which I agreed with and this informed the second series of workshops.

Figure 4.10: Feedback from Reflection with Fellow Doctoral Students

4.4.4 Workshops (Series Two)

The iterative review of the CMOc (figure 4.1) continued with a second series of workshops. Once again, these were scheduled through Doodle Poll, offering a choice of times and I prepared for them in the same way as I had used for the first series and used the same room with refreshments provided. To include all participants, it was necessary to run two workshops with a week between each. The workshop participants are shown in table 4.3).

Table 4.3: Participants in Second Series of Workshops

Workshop 2.1	Workshop 2.2
Data Manager	**Operations Manager**
Operations Manager	**Practice Development Nurse**
Assistant Director of Nursing	**Clinical Nurse Specialist**
Assistant Director of Nursing	**Discharge Coordinator**
Clinical Trials Manager	**Service Improvement Lead**
Senior Medical Scientist	**Project Manager**
Administration Team Manager	**Physiotherapist**
Administration Team Manager	**Data Coordination Lead**
Pharmacist	**Data Coordinator**
Radiology Manager	**Speech and Language Therapist**

These workshops were designed to continue the adjudication of the CMOc derived from the realist review, refined in the first series of workshops and further refined in the individual interviews (figure 4.1). Following introductions, an overview of the development of the CMOc to date was given, and the purpose of the workshop to further adjudicate on the refined CMOc discussed. Following reflection and input from my fellow doctoral students and supervision team, and to facilitate this adjudication, I indicated that the aim was to create a safe space in which to work together in interdisciplinary teams (two teams of five in each of the two workshops) and to design a creative construct to represent teams' further understanding and development of the CMOc. We would again use the CIP principles as part of our ways of working. To facilitate this creativity boxes of creative materials, packs of Evoke© cards and flipcharts (figure 4.11) were provided.

Figure 4.11: A Creative Space

The structured cycle I had utilised in the first workshops worked well, so I adapted this (table 4.4).

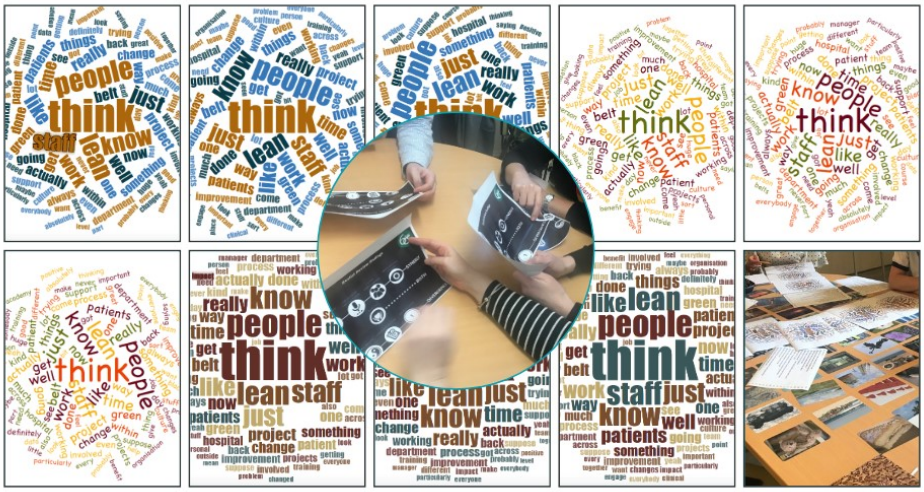
Table 4.4: Cycle for Participant Review of CMOc (Workshop Series Two)

CYCLE	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
1.CONTEXT	15 minute individual reflection	Individual feedback to group	Group discussion	Group work to develop CMOC construct	Group present to other group	Discussion and clarifying questions	5 minute Break
2.MECHANISM	15 minute individual reflection	Individual feedback to group	Group discussion	Group work to create CMOC construct	Group present to other group	Discussion and clarifying questions	5 minute break
3.OUTCOME	15 minute individual reflection	Individual feedback to group	Group discussion	Group work to create CMOC construct	Group present to other group	Discussion and clarifying questions	Sum up and closing activity

Each member of the team was given an individual information pack that contained a map of all of the iterations of the CMOc to date and a word cloud for each iteration

(figure 4.12) to further facilitate reflection. Each pack also contained a copy of the Synergies and Divergence model developed as part of the realist review (figure 2.18). Time was given for the individuals to read through the packs and reflect before discussing within their teams. The word clouds provided a visual reference to key words and themes across all developments in the adjudication to date, from the realist review through the first series of workshops to the interviews. I was on hand throughout to answer any clarifying questions in relation to the materials or intent of the workshop and to assist as required. However, I did not interfere with the teams and left them to develop their own interpretation of the CMOc as it stood, offering input only if requested.

Figure 4.12: Participant Packs



Denning and Verschelden (1993) describe how interdisciplinary workshops and focus groups in healthcare research allow for collaborative conversations that enable the refinement of ideas. This format is particularly useful in realist evaluation as it spotlights participants' attitudes, language and understanding of the CMOc within the framework of their own practice setting (Kitzinger, 1995). Kitzinger (1995) suggests that the interactions between research participants and the researcher allow them to generate and answer their own and each other's questions and to share common experience, which further deepens understanding of the research topic. Feedback showed that these workshops were energising and fun for the participants, as they were for me. At the end of each workshop, the participating teams (n=4) produced a visual

construct for Context, Mechanism and Outcome, based on their individual and team analysis of the CMO iterations to date (figure 4.13). When the final constructs were presented, the participants were referred to the Synergies and Divergence model in their packs (figures 2.17 and 4.12) and asked how their ? finally adjudicated CMOc aligned to it. Participants reflected on this individually, discussed in teams and then presented their findings by mapping the Synergies and Divergence to their final constructs using sticky notes.

Figure 4.13: Creative Adjudication of the CMOc

Through these workshops, the data collected comprised:

1. Constructs and photographs
2. Scribed notes
3. Marked-up Word Cloud booklets
4. Annotated/mapped Synergies/Divergence model
5. Photographic record of workshop
6. Audio-recordings for transcription

Following each workshop, I thanked the participants for their valued participation over the months and reminded them that all data would be anonymised and that their participation and insights would be invaluable in answering the research question. I closed each workshop with use of the Evoke© cards which enabled participants to reflect on the workshop process, how they were feeling and any thoughts they would like to share with the group. I also advised participants to contact me if they had any queries or concerns at any stage and advised them that I would keep them informed as to how the research was progressing and the final outcomes. I again used personal, structured reflection following each workshop to support my own learning and development and to consider the key findings emerging from each workshop.

4.4.5 Review of Results of Participants' Lean Six Sigma Projects

The results of participants' Lean Six Sigma projects have been presented in scientific posters in scientific poster presentations (Appendix 4.1) and peer-reviewed publications (O' Hora et al., 2015; O'Toole et al.2016; Kieran et al., 2016; Hayden et al., 2016; Feeney et al., 2016; Kieran et al., 2017; Brown et al., 2019; Creed et al., 2019; Davies et al.,2019; Hynes et al., 2019; McGrath et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019). These were individually reviewed to illuminate outcomes.

Scientific posters are a common way to present results of a statistical analysis, program evaluation, or other project types at professional conferences (Miller, 2007) and in the

case of this study, the results of participants' Lean Six Sigma project work. Scientific posters offer a unique format, which can be seen as a combination of elements of a published paper and an oral presentation (Miller, 2007). Scientific posters have been shown as a good medium for transferring knowledge and a valid form of academic publication (Rowe & Ilic, 2009). Beilenson (2004) and Briscoe (1996) suggest that scientific posters allow a succinct description of data and methods, with a focus on results, providing enough information for the reader to follow the story line and understand and evaluate your approach and results. Results/outcomes were therefore recorded for each project poster reviewed and subsequently included in overall thematic analysis of the data (section 4.5.1) and imported into NVivo (section 4.5.2). Results/outcomes from participants' scientific publications of their Lean Six Sigma practice area work were likewise reviewed and recorded. Each individual publication was read to evidence the appropriate use of Lean Six Sigma consistent with the DMAIC model (Antony, 2006) and the results/outcomes recorded and again included in the overall thematic analysis of the data (section 4.5.1) and imported into NVivo (section 4.5.2).

A major advantage of this review was that it provided a behind-the-scenes look at a programme that may not have been directly observable. A disadvantage was that it was time consuming; there was a wide variety of project types and each project was evaluated not just for patient outcomes, but also in terms of how it related to existing or newly-generated Contexts, Mechanisms and Outcomes for the CMOc, Lean Six Sigma and Staff . This is discussed in the data analysis section below (section 4.5).

4.4.6 Other Data Collection Methods

As discussed in chapter two, both Lean and person-centred approaches make use of Gemba or observational studies. I considered using either Gemba or observational study as part of this research, as direct observation is a standard ethnographic approach that can allow understanding of behaviour and interactions between health care staff and patients (Gobo, 2011). However, following discussion with my supervision team I decided against this for the following reasons:

- Participants may not have been working on a specific Lean Six Sigma project at the time of the research so there would be no active work to observe
- The diversity of the participants and their practice areas would have an impact in relation to time and cost for the researcher
- Participants had already given on average six hours of their time to the research (including completing consent forms, answering queries and phone calls)
- The results of participants' most recent Lean Six Sigma projects would be reviewed to provide supporting evidence for the outcomes.

The data collection strategy undertaken was therefore both robust and thorough, and it was possible to proceed to data analysis.

4.5 Data Analysis

This section firstly discusses the framework used for data analysis. Secondly, the use of the NVivo qualitative data analysis software used to facilitate coding and thematic analysis of data is outlined. There then follows discussion on validity and rigour which outlines how the CMOc developed during this process. Finally, before concluding and introducing the study findings (chapters five, six and seven) there is reflection on the data collection and analysis process used within this study.

4.5.1 Thematic Analysis

The qualitative data was analysed thematically. In realist evaluation, the units of analysis are the programme theories (the CMOcs) that capture the ideas and assumptions underlying the how and why complex social interventions work (Dalkin et al., 2015). Pawson and Tilley (1997) do not identify any specific method for data analysis; however, previous realist research using realist interviews or focus groups has used thematic analysis (Westhorp, 2008; Thompson, 2012; Mazzocato et al., 2010; Crowley, 2013). The core purpose of data analysis is to ascertain whether and to what extent the research participants 'inspire/validate/falsify/ modify' the programme theory (Pawson, 1996: p 295). Thematic analysis (Braun & Clark, 2006) allows access

to the meaning of the data for the people who generated it (Matthew & Ross, 2010) and can be used to interpret the various aspects of the research question (Boyatzis 1998). Daly et al. (2007) describe thematic analysis as a search for emerging themes from the data that are important in describing the phenomenon. Thematic analysis is the process of identifying patterns or themes within qualitative data and, according to Braun and Clarke (2006), is sufficiently flexible to support the analysis of data collected from interviews, focus groups, workshops, meetings or surveys. For Braun and Clarke's (2006), a theme captures something important about the data in relation to the research question and represents some level of meaning or pattern of response within the data set. Essentially, thematic analysis is a method for the identification and analysis of patterns or themes within data (Braun & Clark, 2006; Matthews & Ross, 2010). This aligns with realist evaluation's concern with outcome patterns that comprise both the intended and unintended consequences of programmes, which result from different mechanisms and different contextual factors. Thematic analysis was therefore useful to facilitate identification and coding of the data generated within each iterative adjudication of the CMOc.

As a method rather than a methodology (Braun & Clarke 2006; Clarke & Braun, 2013), thematic analysis is not tied to a particular epistemological perspective, making it suitable for use by researchers working in different traditions. Gribich (2012) describes thematic analysis as a process of segmenting, categorising and finding links within data prior to any final interpretation. Braun and Clarke (2006, p. 78) suggest that it is a key qualitative method as 'it provides core skills that will be useful for conducting many other kinds of analysis'. Clarke and Braun (2013) suggest that clear guidance is needed for researchers on how to carry out thematic analysis. Indeed, Nowell et al. (2017) suggest that research credibility is dependent on both focus and rigor in carrying out any thematic analysis. Braun and Clark (2006) provide a useful framework to follow (table 4.5).

Table 4.5: Thematic Analysis Framework

Step 1	Become familiar with the data
Step 2	Generate initial codes
Step 3	Search for themes
Step 4	Review themes
Step 5	Define themes
Step 6	Write up

Source: Taken from Braun and Clarke (2006, p.7)

This framework proved useful guidance for analysis and coding of the data generated as the initial programme theory was validated, falsified or modified (Pawson, 1996) by the research participants and as they identified new Contexts, Mechanisms and Outcomes. Thematic analysis starts with 'careful reading and re-reading of the data' (Rice & Ezzy, 1999, p. 258). It is a form of pattern recognition where emerging themes become the categories for analysis. However, in keeping with realist evaluation methodology, the analysis was undertaken, firstly using inductive codes from the data while being alert for data pertaining to themes deductively generated from the CMOc.

Following the first workshop series, I read and re-read the transcripts that I had imported into NVivo and reviewed the imported workbook and photographic archive that I had created for each of them. This was to ensure that I was familiar with the data gathered before moving to the next adjudication of the programme theory. I subsequently repeated this process with the transcripts of the individual interviews and the second series of workshops. I also listened back to the audio-recordings when I wanted to verify how the participants expressed emotion by listening to their tone and delivery. Pomerantz and Fehr (1997) suggest that analysis of transcripts can be strengthened by listening to the audio-recording on which it is based (Mondada, 2007).

In keeping with realist evaluation methodology, the research participants adjudicated the initial programme theory from the realist review and subsequent iterations of the CMOc from each stage of the data collection process (figure 4.1). As part of the thematic content analysis, the data was organised and coded around Context, Mechanisms and Outcomes within existing themes (parent nodes) or created new

subthemes (child nodes) as applicable. Participants' Lean Six Sigma project results evidenced within their scientific posters and publications were coded as applicable to any of the Outcomes (e.g. increase in quality of care and improved patient outcomes) generated from the realist review – workshops – interview – workshops data collection cycle. While thematic analysis was useful in organising and coding notes and transcripts from the various data collection stages, at all times there was cognisance that thematic analysis alone is not sufficient to generate a realist understanding of how and why an intervention works (Wong et al., 2017). The CMOc is used as the main structure for realist analysis (Dalkin et al., 2015; Better Evaluation, 2019) with data organised in relation to the initial and emerging programme theory.

4.5.2 NVivo

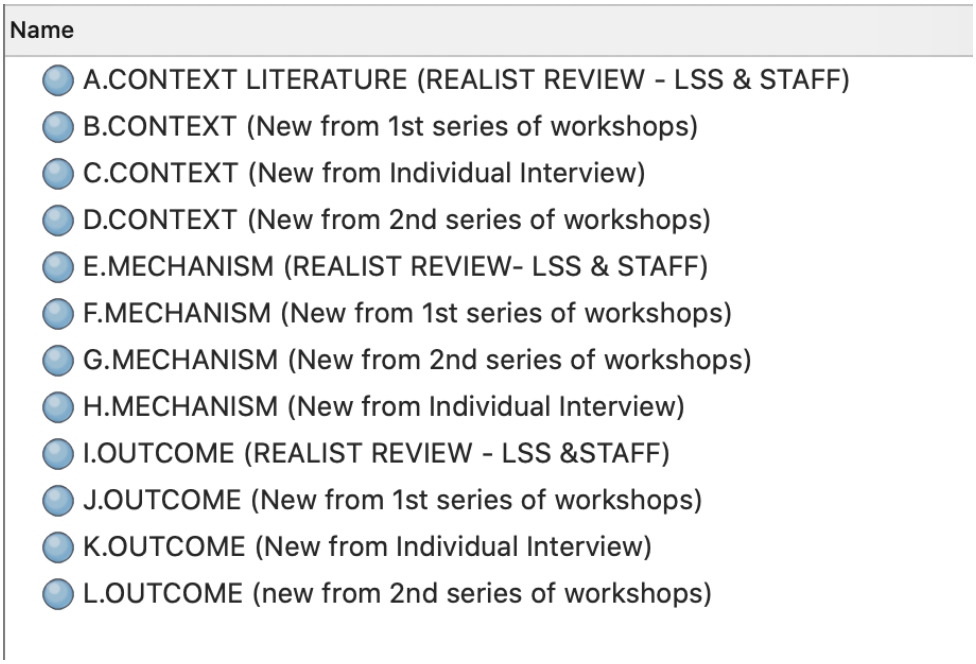
The audio-recordings from both series of workshops and the individual interviews were transcribed, anonymised and imported into the specialised qualitative software, NVivo (Castleberry, 2014), along with initial CMOc from the realist review and scribed notes from the workshops to facilitate coding and thematic analysis of the data. Photographic records of the artefacts and constructs from the workshops were also imported into NVivo. Dalkin et al. (2015) found no literature that specifically discussed methods for NVivo use in realist research; however, they did find evidence of the software's use within realist evaluation (Marchal et al., 2010; Maluka et al., 2011; Douglas et al., 2010). Gilmore et al. (2019) suggest that, despite the increase in the number of healthcare-related realist evaluations, few publications provide details of the methodological processes used. Salter and Kothari (2014) further suggest that little guidance exists on any particular approach to analysis within realist evaluation. Welsh (2002) suggests that software such as NVivo assists the researcher in seeking both transparency and accuracy of collected data while at the same time providing a data analysis audit, which is often a missing component in qualitative research. In realist evaluation NVivo has been used to collate and annotate primary and secondary data sources, aligning evidence from both, and to map the relationships between and within refined programme theories (Copper et al., 2017).

With this in mind and based on the work of Dalkin et al. (2015) and Gilmore et al. (2019), who suggest that NVivo can be useful in preparing both qualitative and quantitative data, the software was used to facilitate data preparation, analysis and coding. A systematic approach was developed to analyse and code data to capture the initial programme theory and subsequent iterations of the CMOc (as developed by participants) and charted their development through the iterative review and adjudication process (figure 4.1).

The approach was as follows:

1. Each data source, the realist review, workshop and interview transcripts, photographic records, results/outcomes evidenced from participant scientific posters and publications were imported and classified by source.
2. A parent node title was created for overarching Contexts, Mechanisms, and Outcomes identified within the realist review (Chapter 2).
3. A child node was created for each individual Context, Mechanism and Outcome identified within the review parent nodes.
4. A parent node was created for Contexts, Mechanisms and Outcomes derived from subsequent adjudications of the theory by research participants in the workshops and interview. At this stage the parent nodes were laid out as shown in figure 4.14.
5. Through review and re-reading of the transcripts and workbooks between each phase of data collection and cumulatively when the data collection was complete, it was possible to identify initial themes emerging from the data.

Figure 4.14: Parent Nodes Created In NVivo



6. Consistent with the approach taken by Dalkin et al. (2015) and Gilmore et al. (2019), child nodes were created if the parent node had undergone any revision during the adjudications as revealed by thematic analysis of the imported transcripts (Braun & Clark, 2006; Berg, 2007). When coding transcripts, new themes that arose from participants' adjudication of the programme theory were identified as deductive codes (Boyatzis, 1998), generating new or refined Contexts, Mechanisms or Outcomes. Simultaneously, inductive codes were assigned to any themes emerging that validated relevant existing Contexts, Mechanisms or Outcomes identified in the realist review (Crabtree & Miller, 1999).
7. Any coding of revised components occurred under the umbrella of the child nodes. This allowed for ease of identification and tracking of the development of the CMOc.
8. Memos and notes were added to each further developed parent node and child node to allow for the development of the CMOc.
9. All parent nodes were set up for aggregate coding of child nodes; this enabled examination of all data for any particular refinement, from any of

the data sources as required (e.g., thematic analysis of a particular interview only or aggregate of interview and workshops across all iterations of the CMOc).

10. Theory refinement occurred from the iterative adjudications of the programme theory that generated any new Contexts, Mechanisms or Outcomes or refined those from the realist review.
11. Finally, for rigour, an extensive process of repeated data analysis was undertaken by reviewing the imported data repeatedly to ensure all segments of text were coded appropriately.

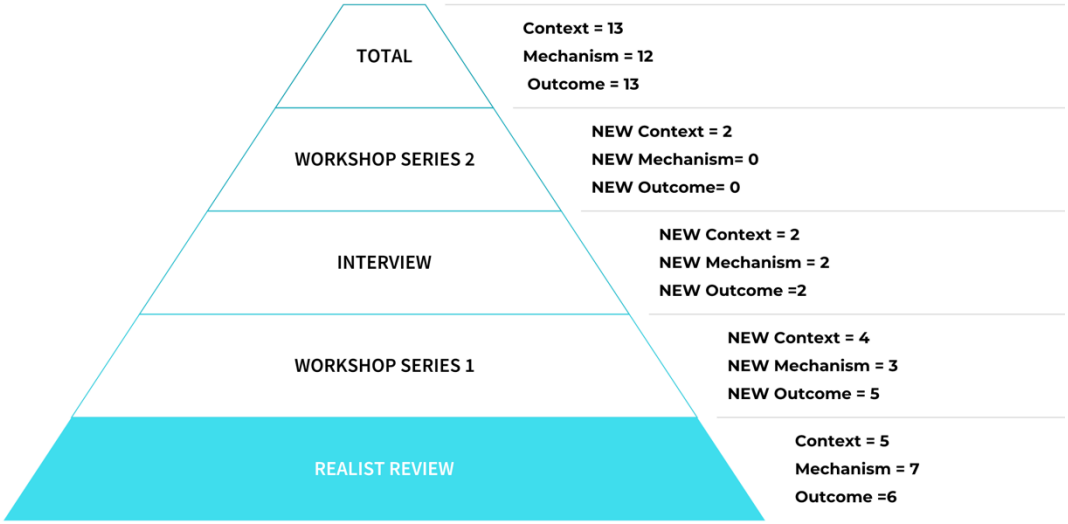
Inclusive of the five Context, seven Mechanisms and six Outcomes contained within the CMOc Lean Six Sigma and Staff (figure 2.21), analysis yielded a total of thirteen Context (C), twelve Mechanism (M) and eleven Outcome (O) nodes (figure 4.15). The participants' review, refinement and development of the initial CMOc, Lean Six Sigma and Staff, through the adjudication process led to the development of three more focused CMOcs as below:

CMOc1. Aspects of organisational culture (chapter five)

CMOc2. The organisation's receptivity to Lean Six Sigma (chapter six)

CMOc3. Participants' self-perception as Lean Six Sigma practitioners (chapter seven)

Figure 4.15: Development of CMOc



4.5.3 Rigour

Wong et al. (2011) suggest that study design and rigour within the research process is key to the overall quality of the research. Realist evaluation proved a highly effective methodology and the methods chosen for data collection and analysis enabled systematic tracking of the outcomes of the Lean Six Sigma programme intervention while allowing me to gain an understanding of participants' experiences of the intervention in their specific contexts and which mechanisms were triggered (Katz et al., 2013). Understanding the experience of the participant is important because, as Charmaz (2005) states

> what observers see and hear depends upon their prior interpretative frames, biographies, and interest as well as the research context, their relationships with research participants, concrete field experiences and modes of generating and recording empirical methods.
> (Charmaz, 2005, p. 509).

The methods of data collection and analysis were congruent with realist evaluation as the nature of the programme intervention as perceived by the research participants was made clear as they identified mechanisms likely to operate in their contexts which could explain how particular outcomes were attained (Pawson & Tilley, 1997). Person-centred approaches to data collection through the use of creative materials, artefacts and CIP principles were essential for understanding and working with participants' values, beliefs and experiences as they related to the intervention of the Lean Six Sigma programme. The pursuit of rigour in this study was influenced by the time spent with the participants, their generation of creative constructs and artefacts and by meticulous recording and processing of the data, enabling the incremental development and refinement of the emerging theory as the data was iteratively analysed (Stake 1995; Pawson 1997). I read and re-read transcripts and reviewed and observed pictorial outputs, and I continually questioned what I brought to data interpretation through the use of reflection (Rolfe et al., 2014; Dewing et al., 2014) and reconnection with the original data. This self-questioning and reflection were captured in a research journal which enabled me to reflect on, understand and record the experiences of both the research participants and myself as a way to ensure rigour within the research. A useful set of criteria (Porter, 2007) for assessing rigour in realist evaluation (Pawson et al., 2003) (table 4.6) was applied to enable me to question myself as to the rigour of the methods of data collection and analysis.

Finally, to focus on my immediate learning from working with participants during the data collection processes, I carried out some more personal reflection. Dewing (2008) suggests that the beginning and the end of the immediate learning process is centred on personal reflection. Congruent with person-centred approaches to learning and development, I carried out some personal reflection on our nearby beach, which during a weekday, was quiet. This enabled me to have some creative reflection and develop a piece of work from driftwood and detritus washed up on a beach, which captured my thoughts on the complexity of the data collection and analysis process and fed forward into structuring the findings (figure 4.16).

Table 4.6: Criteria for Validity and Rigour

Criterion	My reflection
Transparency: is the process of knowledge generation open to outside scrutiny?	Iteratively shared at each adjudication with research participants, supervisors and doctoral studies team at QMU. To be shared via peer-reviewed publication and conferences.
Accuracy: are the claims made based on relevant and appropriate information?	In line with Realist Evaluation, CMOcs developed and theory generated by research participants. There was toing and froing between the raw data and generated explanations that ensures ongoing checking of researcher summaries and explanations.
Utility: are the knowledge claims appropriate to the needs of the practitioner?	All participants meet inclusion criteria and have knowledge of Lean Six Sigma as a basis on which to participate. Knowledge generated will be of benefit to practitioners who want to develop ways of working with Lean Six Sigma congruent with person-centred approaches.
Propriety: has the research been conducted ethically and legally?	Yes. Full ethical approval was granted.
Accessibility: is the research presented in a style that is accessible to the practitioner?	Yes. It will be shared in peer-reviewed publications and conferences and incorporated into the Lean Six Sigma programme at UCD. Findings will be shared with the participant's hospital and group CEO for dissemination.
Specificity: does the knowledge generated reach source specific standards?	Yes, the research follows RAMESES guidelines for carrying out Realist Review/Realist Evaluation and meets the criteria of the RAMESES quality standards.

Source: Adapted from Pawson et al. (2003)

Figure 4.16: Example of author's critical reflection

4.6 Conclusion

This chapter has given an overview of the methods used for data collection, coding and analysis and the rationale for each method. It has detailed the four key methods used for data collection: realist review, facilitated workshops, semi-structured interviews, and a review of the results of participants' most recent Lean Six Sigma projects. It has also discussed how rigour was maintained while undertaking the study.

The next three chapters present the findings in the form of each of the three CMOcs developed from the adjudication of the CMOc, Lean Six Sigma and Staff:

CMOc 1. Aspects of organisational culture (Chapter five)
CMOc 2. The organisation's receptivity to Lean Six Sigma (Chapter six)
CMOc 3. Participants' self-perception as Lean Six Sigma practitioners (Chapter seven)

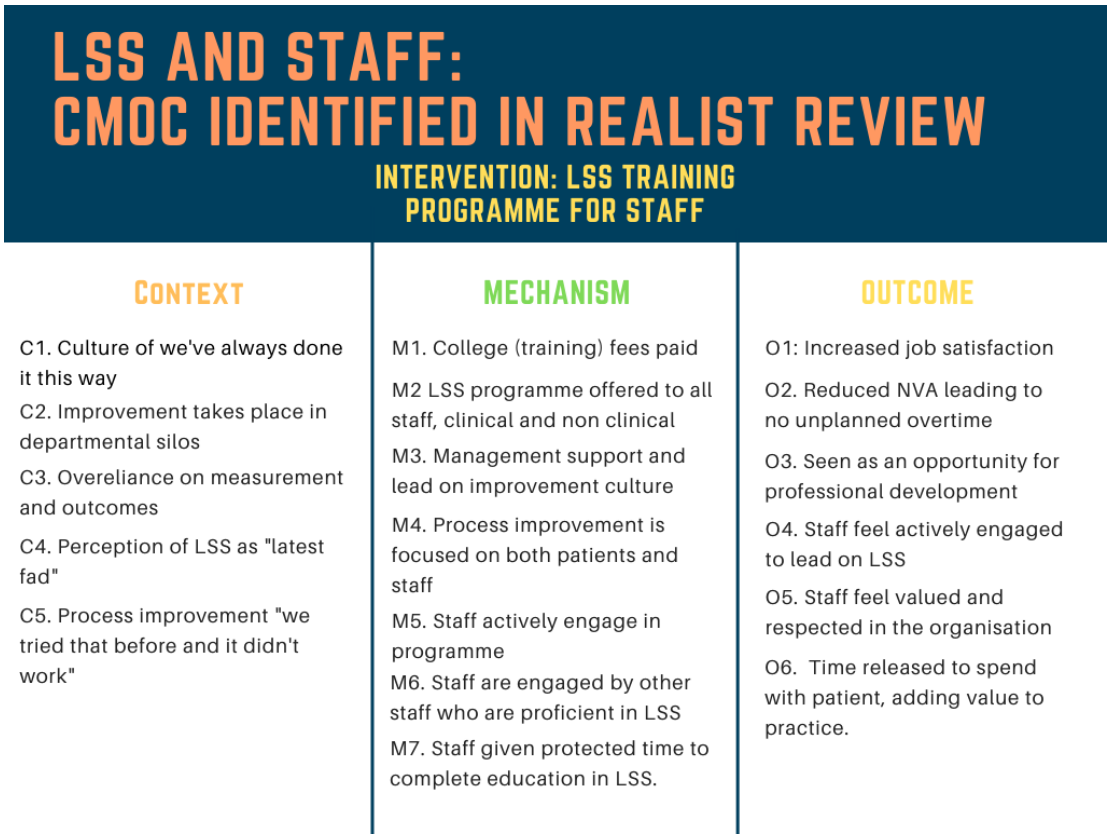
Within chapter five there is now a discussion of CMOc1, aspects of organisational culture.

Chapter 5: CMOc1, Aspects of Organisational Culture

5.1 Introduction

In this and the following two chapters I present the findings of the research, providing an insight into, and understanding of, the participants' experience of the Lean Six Sigma education and training programme. Each findings chapter begins with the CMOc 'Lean Six Sigma and Staff' generated from the realist review (chapter 2) in which five contexts, seven mechanisms and six outcomes were identified (figure 5.1).

Figure 5.1 CMOc 'Lean Six Sigma and Staff' from the Realist Review



Participants reviewed, refined and developed this CMOc through an adjudication process comprising an initial series of workshops, twenty individual interviews and a final workshop series, as outlined in figure 4.15 (chapter 4). This refinement led to the development of three focused or embedded CMOcs:

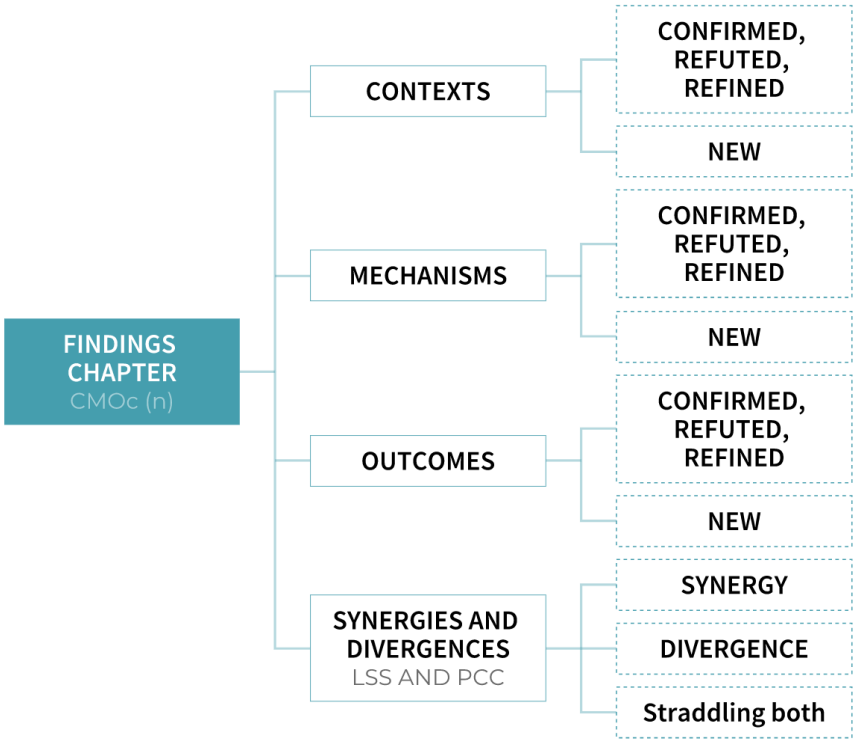
CMOc 1. Aspects of organisational culture (Chapter 5)

CMOc 2. The organisation's receptivity to Lean Six Sigma (Chapter 6)

CMOc 3. Participants' self-perception as Lean Six Sigma practitioners (Chapter 7)

Each chapter is organised into four sections: adjudication of contexts, adjudication of mechanisms and adjudication of outcomes (figure 5.2), followed by a final section describing synergies and divergences between Lean Six Sigma and person-centred care and cultures. The discussion is organised chronologically according to the origin of a particular finding in the adjudication process (figure 4.15). Results from participants' most recent Lean Six Sigma projects are presented as applicable to the initial or adjudicated outcomes identified in the study.

Figure 5.2: Structure of Findings Chapters



As well as confirming, refuting and refining certain contexts, mechanisms and outcomes shown in figure 5.1, participants identified new ones at various stages of the adjudication process (figure 4.15). Congruent with realist evaluation methodology, confirmations, refutations or refinements of the programme theory that facilitate or hinder the effectiveness of the intervention to deliver anticipated outcomes are presented, supported by illustrative quotations from participants that are representative of their collective view (Dobson & Fitzgerald, 2005; Pawson & Tilley, 1997).

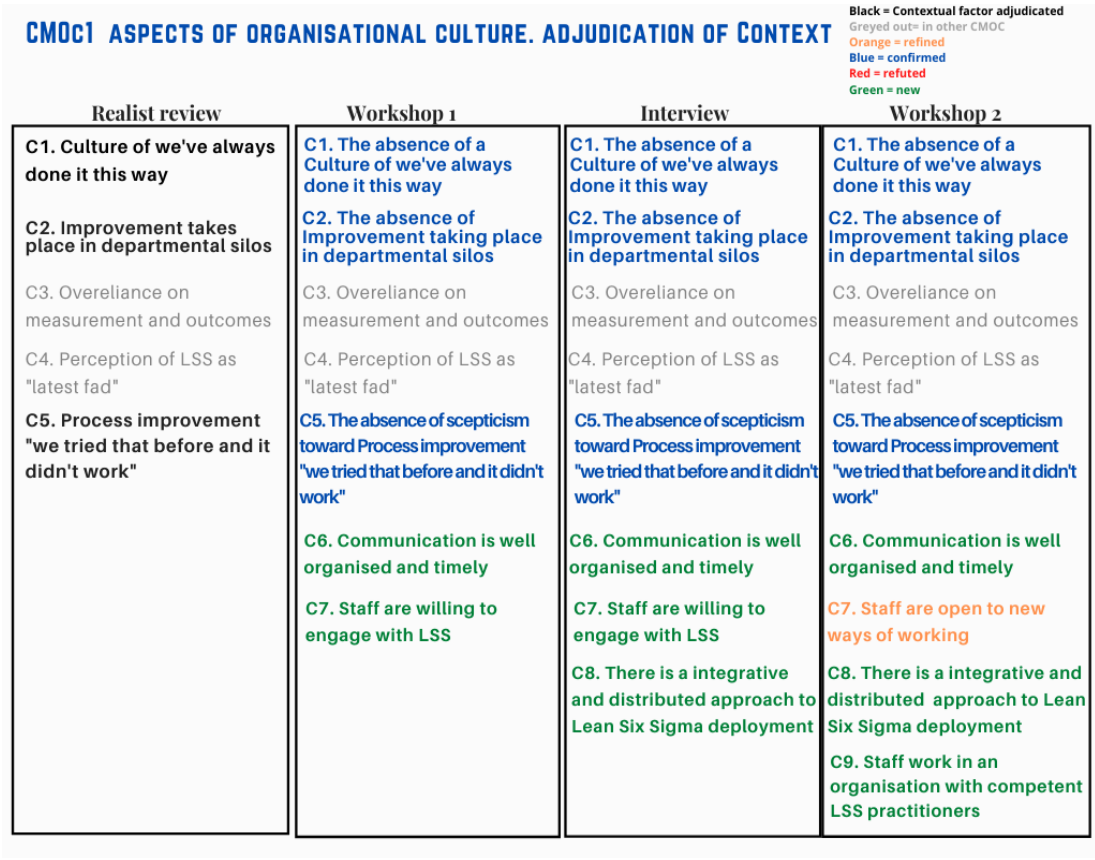
The results of the first focused CMOc, 'aspects of organisational culture' are now discussed.

5.2 CMOc1: Aspects of Organisational Culture

This section begins by presenting participants' adjudication of contexts, mechanisms and outcomes for CMOc1and concludes by considering synergies and divergences of Lean Six Sigma and person-centred care within CMOc1. In this and in each of the subsequent sections, as the relevant Contexts, Mechanisms and Outcomes are discussed, colour coding is used to represent the outcomes of participants' adjudication. This coding is explained in a legend to the right-hand side of each of the relevant figures. Blue, red and orange indicate, respectively, confirmation, refutation and refinement while green refers to new contexts, mechanisms or outcomes.

5.2.1 Adjudication of Contexts for CMOc1

Figure 5.3 CMOc1: Aspects of Organisational Culture - Adjudicated Contexts.



As shown in figure 5.3, in the course of the adjudication process of the CMOc 'Lean Six Sigma and Staff', participants confirmed three contexts (C1, C2, C5) and generated four new contexts (C6, C7, C8, and C9) for the embedded CMOc, 'aspects of organisational culture' (CMOc1). The three confirmed contexts are discussed first, followed by the four new contexts.

5.2.1.1 Adjudication of Contexts for CMOc1: Confirmation

For the CMOc 'Lean Six Sigma and Staff', three contextual factors or features were identified that influenced how staff interacted with Lean Six Sigma deployment within their organisation (figure 5.3):

- Culture of ‘we’ve always done it this way’ (C1).
- Improvement takes place in departmental silos (C2).
- Process improvement ‘We tried that before and it didn’t work’ (C5)

The adjudication of each of these contextual factors for CMOc1 is now discussed in turn.

C1: Culture of ‘we’ve always done it this way’

Some participants had previously experienced a contextual factor of ‘we’ve always done it this way’ within their practice areas. These participants indicated that this had not occurred at an organisational level but rather within some specific practice areas and individual departments:

> there used to be a culture … in the office that we’ve always done it this way…a bit of silo mentality. Since we’ve been involved in the hip fracture and cancer screening [Lean Six Sigma] work that silo mentality has gone.
>
> P1, Data Manager, Workshop 1.

> some of the resistance to change within our unit was very culture driven…they [the staff] felt that they couldn’t change it [the process] because it's not the way it's done around here. That has changed to a large extent as more people feel the benefits from our local [Lean Six Sigma] projects.
>
> P2, Operations Manager, Workshop 1.

However, other participants had not experienced this contextual factor within the organisation or within their individual practice areas:

> not within my section or within the department…people are very open to process improvement.
>
> P5, Senior Medical Scientist, Workshop 1.

> certainly not my experience within physio[therapy] or in my current role.
>
> P6, Discharge Coordinator, Workshop 1.

> there's an openness to change and to try out new things…staff are constantly coming up with new ideas.
>
> P19, Assistant Director of Nursing, Workshop 1.

In the realist review, the contextual factor (C1), "a culture of 'we've always done it this way'", was located at an organisational level, not within specific practice areas. This was not the experience of participants, some of whom experienced this contextual factor, and some of whom did not, but where it had been experienced it was in specific practice areas. Participants further identified that since Lean Six Sigma had been practised within these specific practice areas, that this had changed or was changing. In discussion, participants confirmed that where this contextual factor was present it would hinder how they and other colleagues engaged with Lean Six Sigma, and where it was absent, it would conversely facilitate how they and other colleagues engaged with Lean Six Sigma. It therefore was confirmed as an influencing contextual factor =, mediating mechanisms fired by engagement with the intervention.

C2: Improvement takes place in departmental silos

During adjudication of contextual factor one (C1), the word 'silo' was referred to by participants, therefore indicating some potential overlap with 'improvement takes place in departmental silos'. Participants again conceptualised silo working at two levels, the organisational level and the specific practice area's approach to Lean Six Sigma:

> the cultures that people work in and how improvement takes place …depends what unit you work in.
>
> P3, Assistant Director of Nursing, Workshop 1.

A potential related if not causative factor for departmental silos was identified:

> we … often used to find ourselves operating in a silo because no one…told you what was happening elsewhere. That's really changed since the Lean began.
>
> P9, Clinical Nurse Specialist, Workshop 1.

This ability of Lean Six Sigma to encourage cross-functional teams was noted:

> there's kind of more of a focus now [in this organisation] on collaborative working and you're encouraged to work with other people outside your discipline and practice area.
>
> P2, Operations Manager, Workshop 1.

This more collaborative working was perceived by participants to be facilitated by the Lean Six Sigma education and training programme, and as instrumental in breaking down silos:

> before it [Lean Six Sigma education and training] started...we had no real reason to work closely with departments that were not directly involved with direct patient care. This has changed with more cross directorate team working within [Lean Six Sigma] projects.
>
> P15, Pharmacist, Workshop 1.

> medical secretaries had a more of a support role in the hospital then [before Lean Six Sigma education and training] siloed within their own departments…[I've] worked on eight or nine cross hospital projects at this stage.
>
> P13, Project Manager, Workshop 1.

The contextual factor (C2), 'improvement takes place in departmental silos', had been experienced by participants prior to the introduction of the Lean Six Sigma education and training programme. Participants confirmed that where this contextual factor was present it would hinder how they and other colleagues engaged with Lean Six Sigma. They experienced this siloed way of working as unhelpful but found that Lean Six Sigma enabled it to be addressed. This facilitated participant engagement with the intervention of the Lean Six Sigma education and training programme and seeing the benefit, staff continued to engage with it.

C5: Process improvement 'We tried that before and it didn't work'

In discussing contextual factors one and two, some participants identified that within their practice areas they had previously experienced another contextual factor of 'we

tried that before and it didn't work'. Where this had occurred, participants found this to be hindering to their Lean Six Sigma practice work:

> I do feel like there was a bit of …'What are you going to do differently, we've done that already'…that can be kind of a real barrier.
>
> P7, Service Improvement Lead, Workshop 1.

However, participants felt that in their experience they had an understanding of 'why' staff might feel like they had 'tried this before' whatever the improvement methodology used.

> there was some negativity out there … the staff had been promised so much before, [by the organisation] and there had been some false starts for them [in improvement] … so that when you first bring in something like this [Lean Six Sigma], they are cautious.
>
> P10, Practice Development Nurse RN – Workshop 1.

The local context-specificity of this experience to a particular department, unit or practice area, was again noted:

> we're [participant department] very driven by metrics so Lean Six Sigma is seen as a way to help improve and meet targets…we would willingly participate in improvement work.
>
> P5, Senior Medical Scientist, Workshop 1.

> it depends on where you go…we've embraced Lean Six Sigma within our Directorate...lots of staff trained, projects ongoing, team meetings…other Directorates are at different stages in their Lean journey.
>
> P14, Radiology Manager, Workshop 1.

However, there was general consensus among participants that since the advent of the Lean Six Sigma education and training programme people were more willing to try new ways of working:

> we offer it [White Belt] to all of the staff within our Directorate… once they have this done…[I] think they have an understanding of the need for change and how to manage it.
>
> P8, Administration Team Manager, Workshop 1.

> most staff have had some basic training in it [Lean Six Sigma] at this stage, so I've found there's a willingness to participate in improvement projects.
>
> P10, Practice Development Nurse, Workshop 1.

> there's an interest among staff to involve in Lean Six Sigma projects that wasn't there before I left the hospital. Since I've returned from the UK you can see the change in people and the changes that have taken place here.
>
> P12, Physiotherapist, Workshop 1.

Participants had experienced some instances of staff saying they had 'tried that before' but found that this was the exception rather than the rule. Their experience was that the intervention of the Lean Six Sigma education and training programme had led to a willingness among staff to work in new ways. This suggests that the influence of context is not only one way, but that the intervention and engagement with it starts to change the context. Participants therefore confirmed that where the contextual factor of staff saying 'we tried that before and it didn't work' was present it would hinder how they and other colleagues engaged with Lean Six Sigma, and where it was absent, it would conversely facilitate how they and other colleagues engaged with Lean Six Sigma.

Summary

At the end of the adjudication process, three contextual factors had been confirmed as influential in how people engaged locally with Lean Six Sigma:

- Culture of 'we've always done it this way' (C1).
- Improvement takes place in departmental silos (C2).
- Process improvement 'We tried that before and it didn't work' (C5).

It was where these were absent that positive engagement with the intervention was experienced. They therefore are best expressed and situated in the CMOc as:

The absence of:

- A culture of 'we've always done it this way' (C1).
- Improvement taking place in departmental silos (C2).
- Scepticism towards process improvement 'We tried that before and it didn't work' (C5).

5.2.1.2 New Contexts

While participants confirmed some contextual factors that the literature suggested might influence how staff interacted with the use of Lean Six Sigma in their organisation, they concluded that a number of other contextual factors significantly influenced how Lean Six Sigma was viewed and engaged with:

- Communication is well organised and timely (C6).
- Staff are open to new ways of working (C7)
- There is a structured approach to Lean Six Sigma deployment (C8).
- Staff work in an organisation with competent Lean Six Sigma practitioners (C9).

C6: Communication is well organised and timely

Participants noted that people needed to hear about how Lean could help them with their work as this influenced how they viewed its value to them and their team.

> it's really important that we get the message out there effectively that Lean can help us in our work…the difference it can make to staff and patients.
>
> P5, Senior Medical Scientist, Workshop 1.

They noted however that was always room for further improvement, particularly at communicating with staff directly providing services:

> the organisation needs to continue to communicate consistently with staff…in a timely manner and give them an understanding of what is going on.
>
> P17, Data Coordination Lead, Workshop 1.

> information needs to get down to the people on the ground [the staff], the people that are actually doing the work. The communication should be more regular…always room for improvement.
>
> P2, Operations Manager, Workshop 1.

It was also important that the outcomes of Lean Six Sigma work within the organisation were regularly shared. Not doing so had the impact of discouraging and frustrating those who were working hard to effect change and reducing the likelihood of further engagement across the organisation:

> it can be frustrating if you're doing all this great work and nobody is hearing the good news story.
>
> P13, Project Manager – Workshop 1.

> our [Lean Six Sigma project] team found it incredibly rewarding to see our work acknowledge in the CEO update [hospital newsletter] and to then have our work published.
>
> P9, Clinical Nurse Specialist, Workshop 1.

> new people will continue to train in and use it [Lean Six Sigma] if we continue to get the message out…promote the results [of Lean Six Sigma work] effectively.
>
> P15, Pharmacist, Workshop 1.

Participants were therefore of the view that 'communication is well organised and timely' was a contextual factor that has the potential to positively impact on engagement with Lean Six Sigma. In their discussions there was reference to the influence of praise and reward. This is addressed in CMOc3 'Participants' self-perception as Lean Six Sigma practitioners' (Chapter 7).

C7: Staff are open to new ways of working

In the first series of workshops, participants developed a collective understanding and insight that another contextual factor was important, one of willingness of colleagues to participate. Participants had experienced a willingness among staff to participate or assist with their Lean Six Sigma project work:

> when they did the Stroke project work in ED [Emergency Department] there was an excitement and a buzz around the place…everyone wanted to be involved.
>
> P10, Practice Development Nurse, Workshop 1.

> our project to get patients assessed by an ED Consultant sooner had fantastic staff buy in, we had so many people involved in it.
>
> P3, Assistant Director of Nursing, Workshop 1.

This openness to new ways of working had required making time to meet with and listen to staff involved with or impacted by Lean Six Sigma projects:

> initially had some issues in getting started, but once we sat down and spoke to people and asked them what their feelings were about the project, people relaxed and gave us their time.
>
> P8, Administration Team Manager, Workshop.1.

> time spent meeting staff and explaining our project work…time well spent.
>
> P18, Administration Team Manager, Workshop 1.

> we spend a lot of our time networking, meeting people and getting the voice of the customer, we don't rush in to change without doing this…longer process by far, but you reap the rewards in the end.
>
> P7, Service Improvement Lead, Workshop 1.

This yielded an initial new contextual factor 'staff are willing to engage with Lean Six Sigma'. In the interviews the concept of 'willingness' to assist or participate with Lean Six Sigma work was discussed further. Participants expanded on the idea:

> [The hospital] supports an improvement culture with a focus on patient experience that involves considerable staff input…staff are used to being involved in change, so very willing to assist.
>
> P19, Operations Manager, Interview.

> they [staff] are accustomed to working in cross-functional teams and having their voices heard, so they are giving of their time to invest in improving the way we do things.
>
> P7, Service Improvement Lead, Interview.

Findings from interviews were shared with participants in the second series of workshops and, on adjudication of these, participants refined the initial contextual factor 'staff are willing to engage with Lean Six Sigma'. Cognisant that staff were accustomed to working in cross-functional teams and being involved in the hospital's approaches to quality and process improvement, they refined the contextual factor to 'Staff are open to new ways of working'. Participants felt that this more closely reflected their experiences of working with their colleagues on Lean Six Sigma projects. While the data could at first be interpreted as a mechanism fired by the intervention of the Lean Six Sigma education and training programme, the wider evidence indicated that this contextual factor existed prior to the introduction of Lean Six Sigma and is another example of the bi-directional relationship between contexts and mechanisms. Participants clearly indicated that readiness to change was a result of the experience of, and learning from, the impact of past Lean Six Sigma projects and its presence now enabled active and willing engagement in new Lean Six Sigma projects

During the individual interviews, an additional contextual factor was generated in addition to those generated in the first workshops.

C8: There is an integrative and distributed approach to Lean Six Sigma deployment

A recurring theme in the interviews related to question three (Chapter 4, Appendix 4.6) about Lean Six Sigma work taking place in silos. Participants had undertaken literature reviews in Lean Six Sigma as part of the Lean Six Sigma education and training programme and had a good understanding of organisations that are using Lean

Six Sigma internationally as well as the various approaches to Lean Six Sigma deployment in healthcare (Chapter 2, table 2.4). Participants discussed their own experience of the approach to Lean Six Sigma deployment in the hospital:

> the initial approach seems to have been departmental deployment so Lean was there [in the organisation] in pockets, then with the Lean Academy it went hospital wide, at which point we joined up the pockets.
>
> P13, Project Manager, Interview.

> [I] was on the first [Lean Six Sigma education and training] Green Belt and strategically from the start it was very much about whole hospital training.
>
> P15, Pharmacist, Interview.

Participants had strong views on the importance of a structured introduction of Lean Six Sigma to the hospital environment:

> carried out some Lean work in our department in the 90s, but it was only in our department…industry consultants in to work with us. It was great for a while, then faded away. So, the structured approach of the [Lean Six Sigma education and training] programme is much more inclusive.
>
> P5, Senior Medical Scientist, Interview.

> [we] had some [Lean Six Sigma] work carried out with an external company …didn't really learn anything…did most of the work for us. The [Lean] Academy takes a whole-hospital view of improvement.
>
> P8, Administration Team Manager, Interview.

This whole-hospital, integrative and distributive approach to Lean Six Sigma deployment was seen as important in fostering teamwork and removing silos, which is congruent with the context of an organisational approach to Lean:

> Lean is breaking down silos, because we've all had to dip into different [practice] areas as part of our Lean Six Sigma work.
>
> P18, Administration Team Manager - Interview.

> the way the hospital has introduced it [Lean Six Sigma] has worked well … silos have come down…working together in cross-functional teams.
>
> P14, Radiology Manager – Interview.

Although revisited in workshop two, participants felt that this contextual factor , 'there is an integrative and distributed approach to Lean Six Sigma deployment ' did not require further refinement as it adequately represented their views and experiences.

In workshop two, participants identified a further new contextual factor.

C9: Staff work in an organisation with competent Lean Six Sigma practitioners

In the participants' experience, the presence of competent Lean Six Sigma practitioners (service improvement leads) within the hospital was an important contextual factor for staff engagement with the intervention of the Lean Six Sigma education and training programme.

The value of the Lean Six Sigma practitioners to new staff undertaking process improvement work was evident to the participants:

> [the organisation] has all these trained people … they are capable, know their stuff…respected by new staff undertaking Lean Six Sigma training, because they have walked the walk.
>
> P6, Discharge Coordinator, Workshop 2.

> we have these Lean people who are enthusiastic, and they can mobilise other staff … through that journey of improving the system… having competent Lean Six Sigma people is something important.
>
> P8, Administration Team Manager, Workshop 2.

The Lean Six Sigma practitioners were seen as a repository of knowledge:

> there are barriers to change and to staff engaging with Lean Six Sigma training, but … our Lean trained people are key to helping other staff move forward through the barriers. Working … with a 'bank' of competent practitioners is key.

P12, Physiotherapist, Workshop 2.

The importance of this on-site organisational expertise encouraged staff to engage with Lean Six Sigma and process improvement in general:

> having the Lean Academy on-site…access to expertise and a familiar face, face to face and not via email, very encouraging.
>
> P19, Assistant Director of Nursing, Workshop 2.

The human factor of encouragement and a helping hand were also recognised:

> when I was doing my Green Belt…having…other people who had done Lean Six Sigma already was a great help…an ear to bend and a helping hand.
>
> P11, Discharge Coordinator, Workshop 2.

> being able to meet other practitioners over coffee to pick their brains and asked them for advice was really important to me during my Black Belt [Grad Dip]. And to be able to get help with my Gemba [observational study] really lightened the load.
>
> P15, Pharmacist, Workshop 2.

> I work with data so have been able to help out other teams with their data analysis… able to work on other projects with other teams.
>
> P11, Discharge Coordinator, Workshop 2.

Participants therefore suggested and we all agreed this new contextual factor should be 'staff work in an organisation with competent Lean Six Sigma practitioners'.

Summary

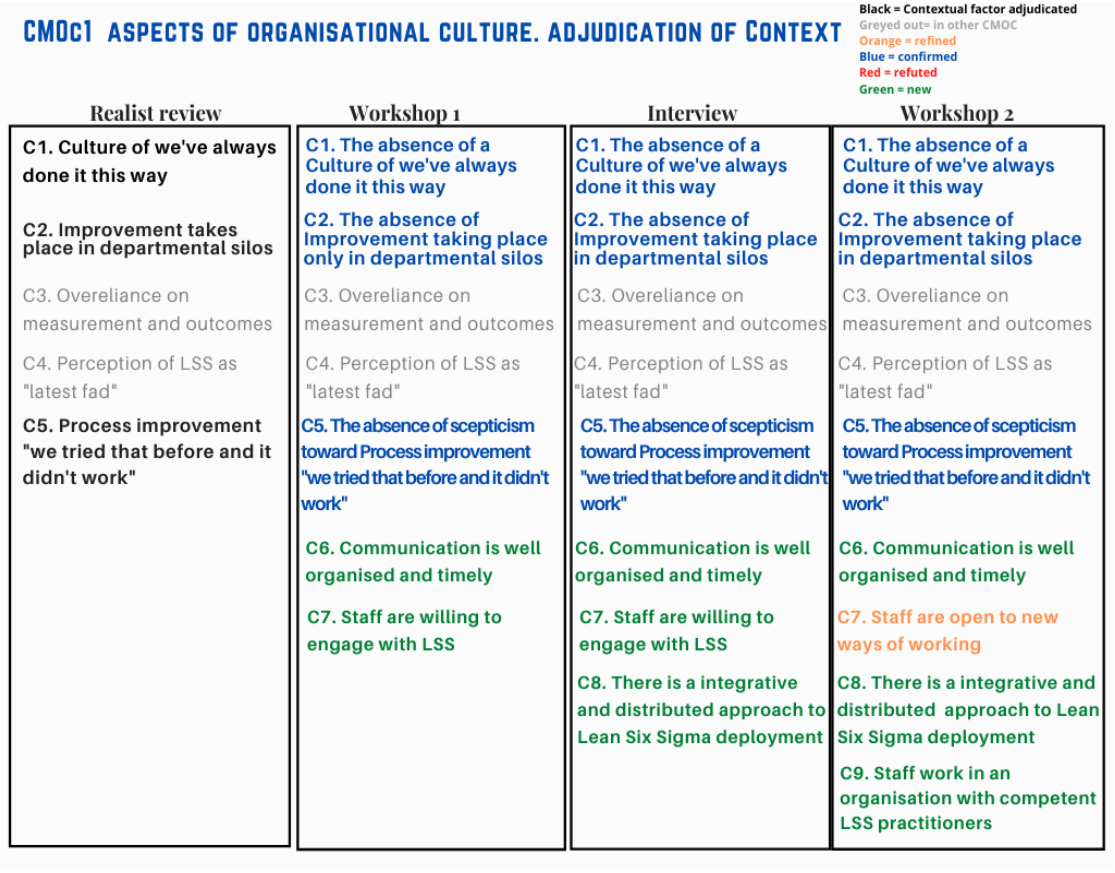
At the end of the adjudication process, four new contextual factors were proposed:

- Communication is well organised and timely (C6).
- Staff are open to new ways of working (C7)

- There is an integrative and distributed approach to Lean Six Sigma deployment (C8).
- Staff work in an organisation with competent Lean Six Sigma practitioners (C9).

5.2.1.3 Overview: Adjudication of Contexts for CMOc1 'Aspects of Organisational Culture'.

Figure 5.3 CMOc1: Aspects of Organisational Culture - Adjudicated Contexts



As shown again in figure 5.3, by the end of the adjudication process, seven contextual factors had been identified as influencing how people engaged locally with Lean Six Sigma. Three contextual factors had been confirmed:

The absence of:

- A culture of 'we've always done it this way' (C1).

- Improvement taking place only in departmental silos (C2).
- Scepticism towards process improvement ‘We tried that before and it didn’t work’ (C5).

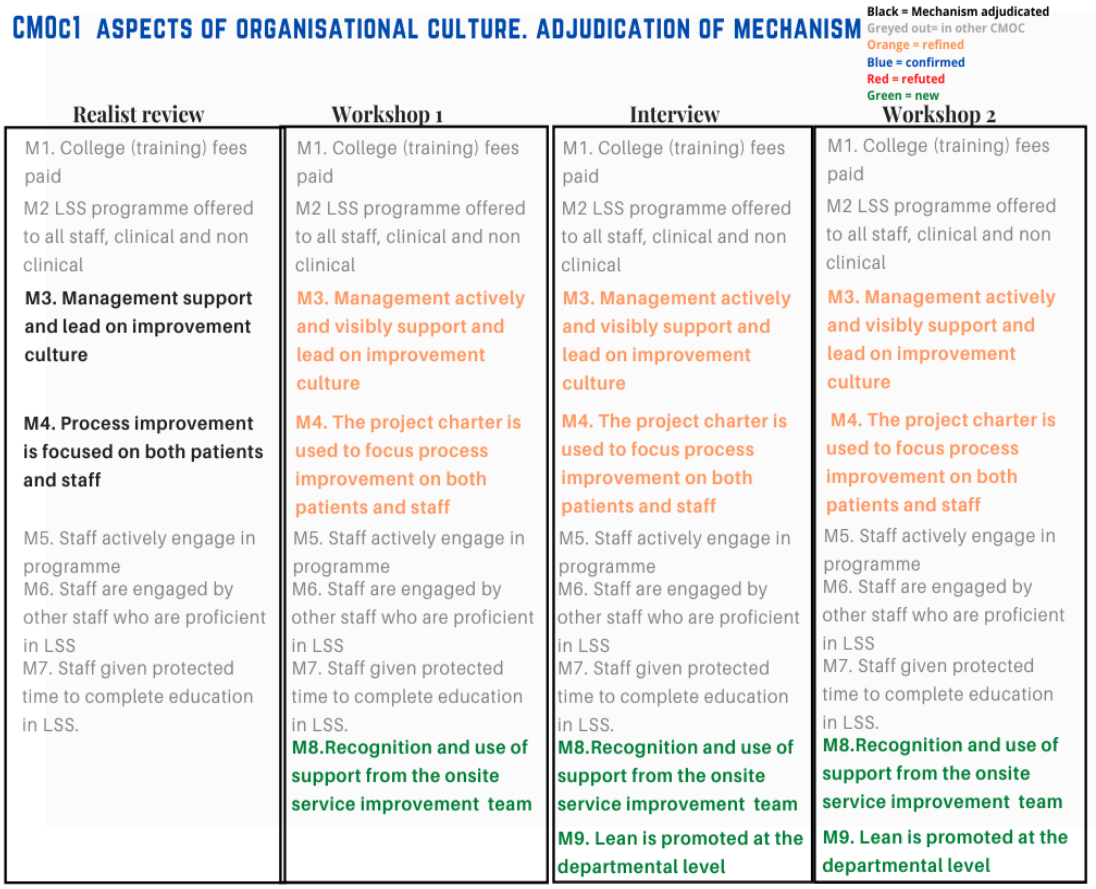
In addition, four new contextual factors were identified:

- Communication is well organised and timely (C6).
- Staff are open to new ways of working (C7)
- There is an integrative and distributed approach to Lean Six Sigma deployment (C8).
- Staff work in an organisation with competent Lean Six Sigma practitioners (C9).

The findings of participants’ adjudication of mechanisms for CMOc1, ‘aspects of organisational culture’ are now presented.

5.2.2 Adjudication of Mechanisms for CMOc1 'Aspects of Organisational Culture'.

Figure 5.4: CMOc1: Aspects of Organisational Culture - Adjudicated Mechanisms



As shown in figure 5.4, in the course of the adjudication process of the CMOc 'Lean Six Sigma and Staff' identified in the realist review, participants confirmed and refined two mechanisms (M3, M4) and generated two new mechanisms (M8, M9) for the embedded CMOc, 'aspects of organisational culture' (CMOc1). The two confirmed and refined mechanisms are discussed first, followed by the two new mechanisms.

5.2.2.1 Adjudication of Mechanisms for CMOc1: Confirmation and Refinement

Participants adjudicated the seven mechanisms from the realist review of literature (figure 5.1) and identified two as resonating particularly with CMOc1 'aspects of organisational culture' (figure 5.4):

- Management support and lead on improvement culture (M3).
- Process improvement is focused on both patients and staff (M4)

The adjudication of each of these mechanisms is now discussed in turn.

M3: Management support and lead on improvement culture

The role of management in supporting both Lean Six Sigma education and training and improvement initiatives by actively promoting improvement work within the organisation was recognised as a key mechanism for Lean Six Sigma practitioners. The Senior Management Team within the hospital were regarded as supportive by participants:

> key enabler for us…senior management support for, and real leadership on improvement culture.
>
> P15, Pharmacist, Workshop 1.

It was felt that management were happy to support improvement work as they saw benefits, not just for patients, but also for the hospital in delivering business cases:

> fantastic support from senior management…results benefit the patients…feed into business cases for more funding [for hospital services].
>
> P2, Operations Manager, Workshop 1.

Some participants stressed the importance of management support as being more than 'verbal assurance':

> difference between management saying they'll…support you as a change agent, and actually supporting you in practice.
>
> P10, Practice Development Nurse - Workshop 1.

> doing a Lean project, you'll hit stumbling blocks and you will often need hands on management support to get over these hurdles.

P17, Data Coordination Lead, Workshop 1.

There was agreement within the group that physical visibility and availability of management in offering support to Lean practitioners was an important factor:

> in Toyota… a mechanism that works for people is support from management who actually lead on improvement culture by walking around, management doing Gemba [observational studies].
>
> P6, Discharge Coordinator, Workshop 1.

There were differing experiences of more specific practice area management support for leading on improvement. Positive experiences within practice areas included those highlighted below:

> when I was in Physio[therapy] she [the manager] was very pro training in Lean…very good about actually allocating time within the working day…allow[ed] project work to be done as well
>
> P6, Discharge Coordinator, Workshop 1.

> it's something [Lean Six Sigma education and training] that I really wanted to do, and I got the support from my managers at the time to apply for it.
>
> Participant 8, Administration Team Manager, Workshop 1.

The variation in level of management support was noted as varying between managers within different participant practice areas:

> when I applied for my Green Belt, I had some issues with access. I think that management support needs to be standardised across the board.
>
> P10, Practice Development Nurse, Workshop 1.

> someone who wanted…training…the unit manager said no outright. Another manager who was subsequently covering from another unit said they could go…the support is varying.
>
> P18, Administration Team Manager, Workshop 1.

The support for further Lean Six Sigma work by practitioners was noted as dependent on the culture within participant specific practice areas:

> her manager said 'you've done enough Lean; we've had enough of change' that's what she was told.
>
> P13, Project Manager, Workshop 1.

The variation in the level of management support experienced by participants led to the refinement of the mechanism from 'management support and lead on improvement culture' to 'management actively and visibly support and lead on improvement culture'. This refined mechanism was discussed again in interviews and in the second series of workshops; however, participants felt that this formulation adequately represented their views and experiences, and no further refinement was required.

M4: Process improvement is focused on both patients and staff

The shift from a focus on improvement in outcomes only for patients to improvement both in outcomes of care for patients *and* in the experiences of patients and staff of care delivery was highlighted as a mechanism relevant to the CMOc, 'aspects of organisational culture'. This dual focus of Lean Six Sigma improvement projects was seen as being instrumental in engaging staff in process improvement:

> recognition of the needs of staff for improvement in their own working day …contributes to more improvement happening.
>
> P2, Operations Manager, Workshop 1.

> the organisation has realised the importance of looking at staff experience…starting to reflect that in its approach to improvement.
>
> P6, Discharge Coordinator, Workshop 1.

This focus on staff and their experiences of Lean Six Sigma in improving processes was considered to be important for staff engagement with Lean Six Sigma:

> able to talk to colleagues who see Lean Six Sigma as improving their own job…able to say to them 'how are you doing? [It's] not just about what benefits the patients, there's a focus on staff as well.
>
> P4, Clinical Trials Manager, Workshop 1.

Practically, this focus on both patients and staff was seen to have a positive impact on participants' practice and their practice areas.

> reduction in staff workload by eliminating duplication has meant a reduction in staff stress…improved staff and patient experiences of the hospital pathways.
>
> P6, Discharge Coordinator, Workshop 1.

In Lean Six Sigma projects, the focus on both service users and care providers is captured by a specific project charter [plan] comprising sections for both patient and staff collaboration, inclusion and participation in project work:

> [the project] charter gives you a steer from the start to engage with everyone involved in the care process, so very useful tool to complete.
>
> P20, Operations Manager, Workshop 1.

> it [the project charter] makes you think about the patient groups you have to talk to, and what staff you will need to meet who are involved in their care.
>
> P19, Administration Team Manager, Workshop 1.

The charter is completed prior to every Lean Six Sigma project:

> the team complete it [the project charter] in their 'forming stage' and it functions as a roadmap for your project.
>
> P9, Clinical Nurse Specialist, Workshop 1.

The charter is iterative and updated by the team at all stages of the project, ensuring there is a continuing focus on both care providers and service users:

> we update it [the project charter] as we move through specific projects to make sure that we are not leaving anyone out of the loop.
>
> P 7, Service Improvement Lead, Workshop 1.

The discussion of the project charter led to participants refining the mechanism identified in the realist review to take account of the charter in their Lean Six Sigma work. Participants therefore refined the mechanism from 'process improvement is focused on both patients and staff' to 'the project charter is used to focus process improvement on both patient and staff'. Again, this refined mechanism was discussed in subsequent adjudications, but participants felt that the mechanism now adequately represented their views and experiences, and no further refinement was required.

Summary

At the end of the adjudication process (figure 5.4), two mechanisms had been refined from:

- Management support and lead on improvement culture (M3).
- Process improvement is focused on both patients and staff (M4).

to:

- Management actively and visibly support and lead on improvement culture (M3).
- The project charter is used to focus process improvement on both patient and staff (M4)

5.2.2.2 Adjudication of Mechanisms for CMOc1: New Mechanisms

In the adjudication process, two new mechanisms for CMOc1 were identified:

- Recognition and use of support from the on-site service improvement team (M8)
- Lean is promoted at the departmental level (M9)

Each is now discussed in turn.

M8: Recognition and use of support from the on-site service improvement team

In the first workshop series, participants suggested that the on-site service improvement team within the hospital had encouraged people to engage with Lean Six Sigma:

> having the [service improvement] team on-site in the hospital…quite forward thinking…a supportive staff environment…positive culture for change.
>
> P7, Service Improvement Lead, Workshop 1.

This development by the organisation of an on-site team of process improvement practitioners showed an awareness that improvement and change is often perceived as hard and staff need support in adapting to change:

> [The] service improvement team… shows that we are working in an environment that is forward thinking, wanting to be innovative…realises people need help with change.
>
> P11, Discharge Coordinator, Workshop 1.

The participants' experience of the on-site service improvement team was seen as an investment by the organisation in staff:

> if I need a bit of help with it [process improvement] then that would be when I go to the Lean Academy.
>
> P5, Senior Medical Scientist, Workshop 1.

Other participants also valued the resource of the service improvement team:

> it's a great resource to tap into and sort of figure things out
>
> P6, Discharge Coordinator, Workshop 1.

The participants spoke about a sense of community that the service improvement team has fostered for Lean practitioners.

> positive staff engagement and relationship…met a lot of people through the improvement programme; it's like a network or a community.

P6, Discharge Coordinator, Workshop 1.

There was no further refinement of this mechanism in the interviews or in the second series of workshops as participants felt that the mechanism now adequately represented their views and experiences and no further refinement was required. However, an additional mechanism was generated from the interview data.

M9: Lean is promoted at the departmental level

During the interviews a new mechanism was generated related to CMOc1, 'aspects of organisational culture'. Participants spoke of how they promoted Lean in their practice areas:

> we actively promote Lean within the Directorate for our nurses. I think once people do some Lean, they appreciate the role they have to play in change…we [the senior nursing team] promote it.
>
> P19, Assistant Director of Nursing, Interview.

> anyone who wants to go on White Belt training I support.
>
> P14, Radiology Manager, Interview.

However, it was evident that there was promotion of Lean at a departmental level, not just by the participants themselves:

> have an improvement suggestion board in the department and we work off these in our Quality group.
>
> P5, Senior Medical Scientist, Interview.

> three of us were funded this year to do the Black Belt and all of us work in departments were Lean is well supported and also well-advertised…allows them[staff] to access these [Lean Six Sigma education and training] opportunities
>
> P12, Physiotherapist, Interview.

Participants felt that the interdisciplinary nature of Lean Six Sigma facilitated its promotion across departments and disciplines:

> we promote this across all of the HSCP [Health and Social Care Professions], Physiotherapist, OT[Occupational therapy], Speech and Language Therapist and all the others.
>
> P8, Administration Team Manager, Interview.

This department-level promotion was seen as an important mechanism for staff engagement with Lean Six Sigma. However, participants still saw the need for improvement:

> we need to have every unit promoting Lean or talking about it so people can engage.
>
> P20, Operations Manager, Interview.

This new mechanism, generated in the interviews, was adjudicated in the second workshop series, but participants felt that the mechanism adequately represented their views and experiences, and no further refinement was required.

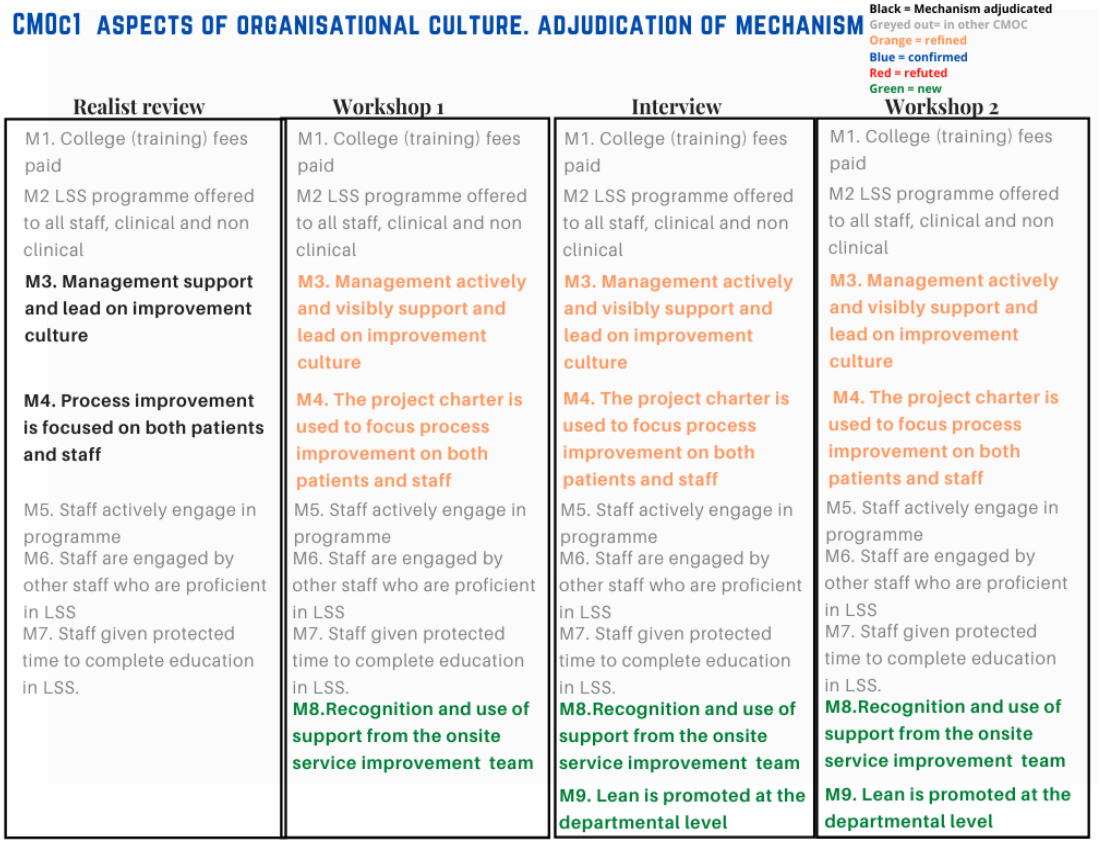
Summary

Two new mechanisms were identified in the adjudication process (figure 5.4):

- Recognition and use of support from the on-site Lean team (M8)
- Lean is promoted at the departmental level (M9)

5.2.2.3 Overview: Adjudication of Mechanisms for CMOc1 'Aspects of Organisational Culture'

Figure 5.4 CMOc1: Aspects of Organisational Culture - Adjudicated Mechanisms



As shown again in figure 5.4, at the conclusion of the adjudication process, two mechanisms had been refined from:

- Management support and lead on improvement culture (M3).
- Process improvement is focused on both patients and staff (M4).

to:

- Management actively and visibly support and lead on improvement culture (M3).
- The project charter is used to focus process improvement on both patient and staff outcomes (M4).

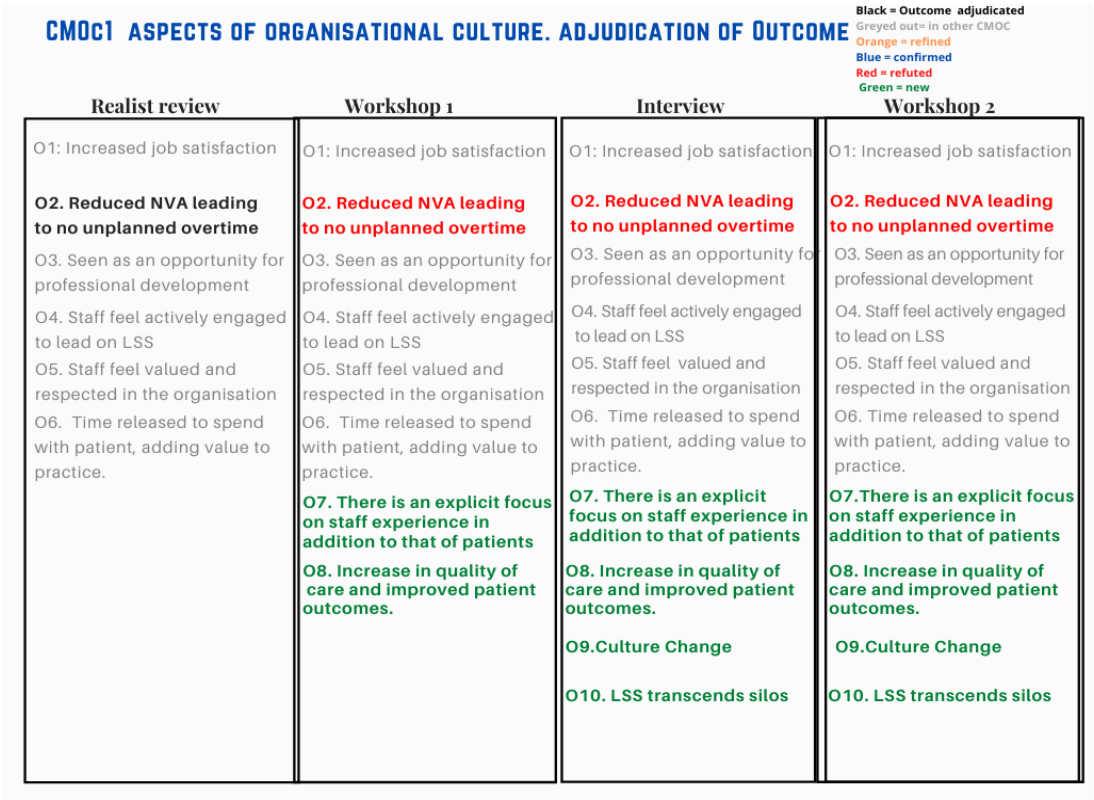
In addition, two new mechanisms had been identified:

- Recognition and use of support from the on-site service improvement team (M8)
- Lean is promoted at the departmental level (M9)

The findings of participants' adjudication of outcomes for CMOc1, 'aspects of organisational culture' are now presented.

5.2.3 Adjudication of Outcomes for CMOc1 'Aspects of Organisational Culture'.

Figure 5.5 CMOc1: Aspects of Organisational Culture - Adjudicated Outcomes



As shown in figure 5.5, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants refuted one outcome (O2) and generated four new outcomes (O7, O8, O9, O10) for the CMOc, 'aspects of organisational culture', (CMOc1). The refuted outcome is discussed first, followed by

the four new outcomes. This is followed by discussion of participants' Lean Six Sigma project results that provide supporting evidence for the outcomes.

5.2.3.1 Adjudication of Outcome for CMOc1: Refutation

As shown in figure 5.5, participants adjudicated the six outcomes from the realist review and refuted one:

- Reduced NVA leading to no unplanned overtime (O2)

This outcome is now discussed.

O2: Reduced NVA leading to no unplanned overtime

Participants felt that this outcome focused more on organisational control of overtime to reduce cost rather than on their experience and the length of their working day:

> [I] can't say that I recognise this as an outcome for me personally… it's an organisational cultural thing to get managers not to have overtime in the current climate.
>
> P9, Clinical Nurse Specialist, Workshop 1.

> haven't seen the outcome of reduced overtime – maybe some others have but I definitely haven't.
>
> P13, Project Manager, Workshop 1.

The difference between the staff and management understanding of reduced overtime was emphasised:

> the emphasis for them [management] is on the cost savings – reducing overtime and coming in on budget. I think for us [staff] it's more about trying to give people the time to do the things they have to do.
>
> P19, Assistant Director of Nursing, Workshop 1.

Participants generally felt that any time released was focused on patients rather than budgets:

> using Lean to free up time for therapists…spend more time with patients. I'm not thinking budget or overtime, but maybe I should be.
>
> P12, Physiotherapist, Workshop 1.

> it's about time wastage and… freeing up time to do my own work and then that work impacts on patient outcomes, and of course on my colleagues working day too.
>
> P3, Assistant Director of Nursing, Workshop 1.

However, the use of Lean Six Sigma in freeing up time was not disputed, and many participants had participated in and delivered projects which had released time to care.

The experience of participants of Outcome 2 was that they had not encountered it as an aspect of their organisational culture and that it was not salient for them in their Lean Six Sigma practice. Rather, all participants emphasised patient outcomes and staff and patient experiences of care. The participants therefore refuted this outcome during the first series of workshops.

Summary

At the end of the adjudication process, one contextual factor was refuted:

- Reduced NVA leading to no unplanned overtime (O2)

5.2.3.2 Adjudication of Outcomes for CMOc1: New Outcomes

In the adjudication process, four new outcomes were identified :

- There is an explicit focus on staff experience in addition to that of patients (O7)
- Increase in quality of care and improved patient outcomes (O8)
- Culture change (O9)
- Lean Six Sigma transcends silos (O10)

Each is now discussed in turn.

O7: There is an explicit focus on staff experience in addition to that of patients

Participants suggested that an important outcome was the explicit focus on the staff experience of Lean Six Sigma work:

> [I] have certainly felt this focus on staff on my [Lean] journey…the investment from the CEO and her team in us.
>
> P5, Senior Medical Scientist, Workshop 1.

> key part of all of our [Lean Six Sigma] work has been an organised 'what worked/what didn't work' session reflecting on what has happened so we can understand how and what to improve.
>
> P 9, Clinical Nurse Specialist, Workshop 1.

The experiences of staff involved in and affected by Lean Six Sigma project work was considered to be an important outcome:

> even small changes can have lasting impacts on staff…the Lean Six Sigma improvement we worked on there [a practice area] wasn't massive but it had an impact on the entire service.
>
> P2, Operations Manager, Workshop 1.

> for me, outcomes for staff…their experiences of Lean Six Sigma and caregiving have got to be foremost in our minds when looking for results.
>
> P19, Assistant Director of Nursing, Workshop 1.

Recognition of staff experiences, and how Lean Six Sigma work could benefit them, was regarded as important in improving staff stress levels:

> [the] rehab project resulted in a reduction in stress for staff by reduction in duplication of reports and paperwork…improved staffing and patient experiences of hospital pathways is a major outcome.
>
> P6, Discharge Coordinator, Workshop 1.

> [Lean Six Sigma] is creating an environment that is more efficient but less stressful for staff then that is an outcome everybody can buy into.

P15, Pharmacist, Workshop 1.

The outcome of a focus on both patients and staff was appreciated for its importance in recognising staff as instrumental to the quality of care that patients receive:

> medical scientists are happier in their work but correspondingly they now have better specimen TAT [Turn Around Times] for patient results.
>
> P5, Senior Medical Scientist, Workshop 1.

> the [Lean Six Sigma] programme has been a great experience…[I] finished it [the programme] with a good knowledge of how to adopt Lean Six Sigma practices in my everyday work, to the benefit of patients and my colleagues.
>
> P15, Pharmacist, Workshop 1.

And the staff experience of working with Lean Six Sigma to improve patient outcomes was recognised as important:

> [I'm] starting to see the benefits of the focus on the staff experience of Lean Six Sigma interventions - happier staff, happier patients and you really get to improve your network and your relationships.
>
> P 7, Service Improvement Lead, Workshop 1.

> [the] skills, knowledge, confidence and experience I have gained from the [Lean Six Sigma] project has enabled me to appreciate my role and the role of multi-disciplinary teams in managing change in an increasingly challenging healthcare environment.
>
> P5, Senior Medical Scientist, Workshop 1.

Participants discussed this new outcome, 'there is an explicit focus on staff experience in addition to that of patients', in the interviews and in the second series of workshops; however, there was no further refinement of this outcome as participants felt that it adequately represented their views and experiences, and no further refinement was required.

O8: Increase in quality of care and improved patient outcomes

Participants felt that an important outcome evident in the realist review but not in in relation to the CMOc, 'Lean Six Sigma and Staff', was that they had experienced an 'increase in quality of care and improved patient outcomes'. They indicated that, although this was important for patients, it also had a huge impact on them as staff members:

> [I] understand from what you say that this is represented in the 'Lean Six Sigma and Patients' table [another CMOc from realist review] but I think it's important to reflect in our discussion about staff.
>
> P7, Service Improvement Lead, Workshop 1.

> totally…huge impact on staff…generates such positivity when our patients do well and receive excellence of care.
>
> P12, Physiotherapist, Workshop 1.

The importance attached to the quality and experience of patient care was recognised at an organisational level:

> huge organisational push…national push to align to the HIQA [Health Information and Quality Authority] guidelines, so quality as an outcome is definitely important.
>
> P3, Assistant Director of Nursing, Workshop 1.

> quality is foremost on the mind of management…the hospital prides itself on the excellent care it delivers.
>
> P19, Assistant Director of Nursing, Workshop 1.

The important role of hospital staff in achieving this outcome of quality care and improved patient outcomes was seen as paramount in delivering improvement:

> I jot down every good idea I hear and this to me is part of quality improvement…everyone in the hospital has a role to play in delivering an outcome of quality care.
>
> P7, Service Improvement Lead, Workshop 1.

The Lean Six Sigma education and training was seen as important in giving staff the skills to work towards this outcome:

> many Belts [Lean graduates] participated in our Rehab care pathway project…working together as a team and thinking about how we could reduce our LOS [Length of Stay] for patients' going to rehab…they have reduced it by eight days…redesigning the systems and prioritisation for frailer patients.
>
> P6, Discharge Coordinator, Workshop 1.

Quality and improved patient outcomes were a recurrent theme for participants within the workshop:

> [the Lean Six Sigma project team] shortened the drug round …less follow ups for pharmacy…released nursing time to care…spend more time spent with their patients…definitely improved both the staff experience and the quality of care.
>
> P15, Pharmacist, Workshop 1.

This new outcome was discussed again in the interviews and in the second series of workshops; however, participants felt that this formulation adequately represented their views and experiences, and no further refinement was required. However, a further two outcomes were generated during the interviews.

O9: Culture change

Participants advised that, in relation to the contextual factors and mechanisms they had adjudicated in the workshop, an additional outcome they had experienced was 'culture change'. The change was felt at an organisational level:

> the culture has changed since it [Lean Six Sigma] has come in…teams mixing and staff mixing across disciplines and working on projects.
>
> P7, Service Improvement Lead, Interview.

> [Lean] has crossed departments and grades … the impact on the culture around the place is noticeable.
>
> P 11, Discharge Coordinator, Interview.

> [I] feel like the overall trajectory is …of an improvement culture and I think that's really good compared to other places that I have worked.
>
> P12, Physiotherapist, Interview.

Staff were interested in involving in change:

> [I] would say … that the culture has changed…most people who are engaging in a Lean project have tried it already themselves, so they are quite eager to try and do something using Lean.
>
> P15, Pharmacist, Interview.

Participants felt that team culture had changed:

> [staff] look for failure in a process as opposed to the people involved …. the blame culture in the hospital is not as prevalent.
>
> P4, Clinical Trials Manager, Interview.

> the dynamic between managers and staff has changed. In general, managers are more open to letting their staff come up with solutions to problems. Now the team as opposed to the individual solves the problem…(Lean Six Sigma) changed the culture.
>
> P19, Assistant Director of Nursing, Interview.

Individuals felt the personal impact of this culture change:

> in the time since I went and came back to Ireland, the culture has changed in the hospital. I notice it in my department… it [Lean Six Sigma]is open to all on an equal basis.
>
> P12, Physiotherapist, Interview.

Participants felt that the Lean Six Sigma intervention had a direct influence in the Culture Change:

> there has definitely been a shift in culture … a huge amount of that is attributed [to] the Lean academy … we're training more and more staff. … having a Lean academy sort of makes it more straightforward.

P4, Clinical Trials Manager, Interview.

No further refinement of this outcome took place as participants felt that it adequately represented their views and experiences.

O10: Lean Six Sigma transcends silos

Participants agreed that Lean Six Sigma enabled staff to transcend silos particularly where the mechanisms they had confirmed, refined and generated were present, and where the new contextual factors they had generated were present; that is,

- Communication is well organised and timely (C6)
- Staff are open to new ways of working (C7)
- There is an integrative and distributed approach to Lean Six Sigma deployment (C8).
- Staff work in an organisation with competent Lean Six Sigma practitioners (C9).

Participants were asked about any individual experiences of encountering silos of Lean Six Sigma improvement and if they had, why they thought these silos occurred and could be managed:

> [a Lean Six Sigma project in scheduled care] involves all staff who are involved with scheduling of patients at some level, it crosses directorates, it crosses silos…silos are broken down by the scope of the specific project.
>
> P13, Project Manager, Interview.

> my Green Belt and many of the Green Belts… trying to improve waiting lists and waiting times. The Green Belt was like a way in to breaking down the silos.
>
> P2, Operations Manager, Interview.

The understanding of 'silo' was considered important. One participant noted the importance of referring to siloed thinking as opposed to physical silos.

> [We] need to understand the difference between required speciality care and siloed thinking…a culture shift in the time since I left and came back to the Mater, far more open, less siloed thinking.
>
> P12, Physiotherapist, Interview.

Another participant raised a similar point.

> silo is not just talking about individual areas or departments, it includes…not being inclusive or being included.
>
> P5, Senior Medical Scientist, Interview.

Participants highlighted the role of Lean Six Sigma interventions in bringing people together. This was seen to have an impact on team culture, with a corresponding breakdown in silos.

> you now see people from all disciplines from across the hospital with the same goal to improve process …all on the same page.
>
> P11, Discharge Coordinator, Interview.

> the frailty groups [frail elderly care pathways] that we do are cross-disciplinary and even cross-site and you see that there has been a lot delivered that isn't siloed.
>
> P16, Speech and Language Therapist- Interview.

The intervention of Lean Six Sigma was again and again highlighted as having an impact on an outcome of transcending silos.

> [I] could see the difference it [Lean Six Sigma] would make to me in my working day, my colleagues…our patients. …moved me out of my little box.
>
> P13, Project Manager, Interview.

> [I've] learnt a huge amount on our Gemba (observational studies) going to areas where I wouldn't have any business to be otherwise.
>
> P1, Data Manager, Interview.

Returning to the theme of silos of people as opposed to silos of places, participants experienced changes in people's behaviour.

> data we collected and presented, the observational study data and the patient stories had a profound impact on even the most routinised of my own nursing colleagues. People who were opposed to our improvement suddenly became the biggest advocates.
>
> P19, Assistant Director of Nursing, Interview.

The outcome was reviewed again in the second series of workshops but participants felt that it adequately represented their views and experiences, and no further refinement was required. This outcome in turn changes the future context within which Lean Six Sigma will operate, contrasting with contextual factor C2, improvement takes place in departmental silos.

Summary

Four new outcomes for CMOc1were generated in the adjudication process (figure 5.5):

- There is an explicit focus on staff experience in addition to that of patients (O7)
- Increase in quality of care and improved patient outcomes (O8)
- Culture change (O9)
- Lean Six Sigma transcends silos (O10)

The results of participants' Lean Six Sigma projects that are relevant to the outcomes they generated in the adjudication process are now presented.

5.2.3.3 Analysis of Lean Six Sigma Project Results that Provide Supporting Evidence for the Outcomes for CMOc1, 'Aspects of Organisational Culture'.

Two participants (coded as 7 and 15) had worked as part of a multidisciplinary team, including nurses, pharmacists, improvement leads and quality staff, to complete a project that released nursing time to care, specifically relieving pressure on nursing and pharmacy staff by improving controlled drug delivery processes. There was a

statistically significant 44% decrease in nurse journeys to pharmacy for drug collections, which was maintained after eighteen months and continues to time of writing (July 2020) (Creed et al., 2019). This provides evidence of a focus on staff as well as patient experience and improvement in the quality of patient care (outcomes O7 and O8).

Another two participants (coded 9 and 14) had been part of an interdisciplinary team of administrators, radiologists, nurses and cardiac physiologists who participated in a project to improve rates of remote cardiac monitoring. The team set out to look specifically at staff experiences and to engage with staff, to invest in them and to show them their value from the organisation's perspective. Prior to implementation, the cardiac clinic was processing 102 remote monitoring (RM) follow-up checks with a mean of 140 unscheduled attendances per month. Following implementation, RM enrolment increased to 335 follow-up checks (194% increase), with 41 unscheduled attendances on average per month (70% decrease). These results were sustained one year after implementation and, as well as improving patient access to cardiac monitoring, significantly improved staffs' experience of clinics (Ryan et al., 2019). The results provide further evidence of a focus on staff as well as patient experience and the improvement in quality of patient care as suggested for outcomes O7 and O8.

Participant 8 had participated in a project to improve the efficiency of a private hospital's day care unit and achieve a positive impact on optimising nursing time and improving patients' experience of their day care. The project evaluation highlighted significant improvements in service performance and patient and staff satisfaction, including an increase in the nurse-patient ratio (Davies et al., 2019). This project involved before and after patient and staff satisfaction surveys, again demonstrating to staff that there was a focus on improving care delivery for them as well as their patients. This project provides more evidence of a focus on staff as well as patient experience and improvement in quality of patient care as suggested in outcomes O7 and O8.

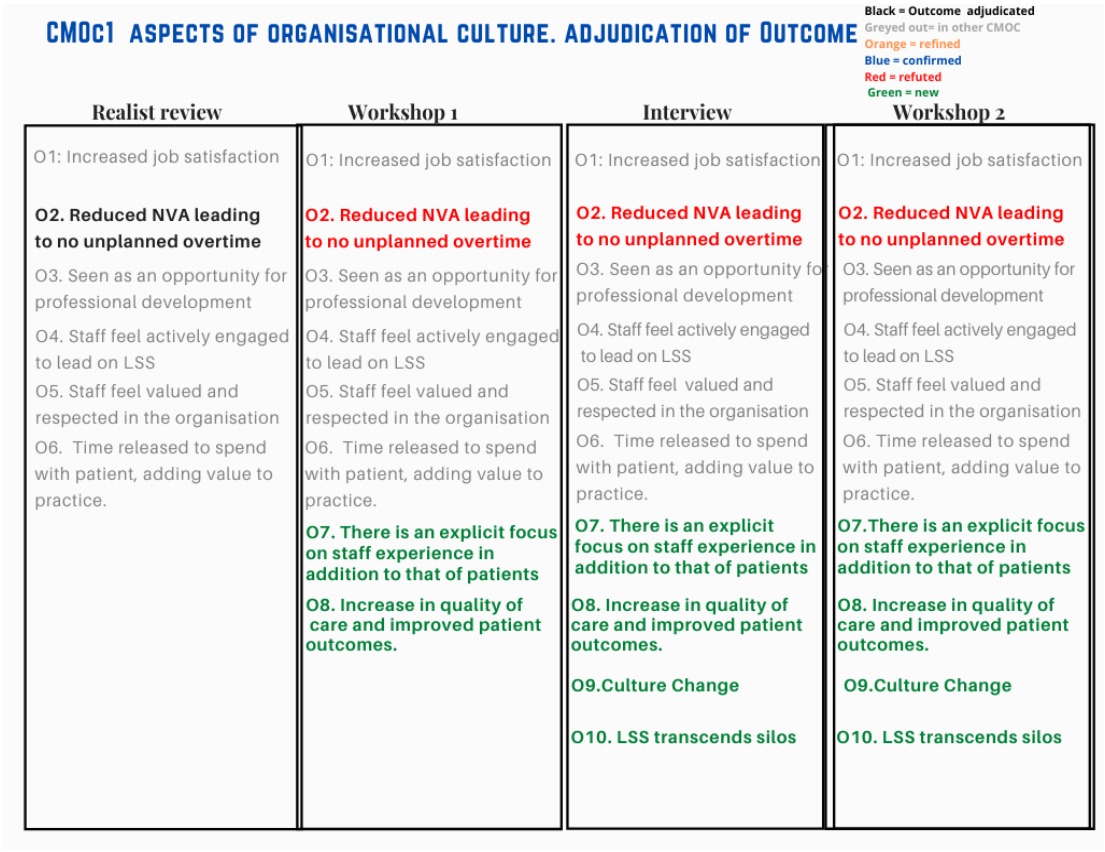
Participant 16 had participated in numerous Lean Six Sigma projects and continues to use Lean Six Sigma in practice. An interdisciplinary team project on nutrition and hydration for people who had had a Cerebrovascular Incident (stroke) demonstrated effective teamwork, which quickly overcame silo thinking (outcome O10) and engaged and supported each other with a high challenge, high support approach (Teeling et al., 2019). This project also contributed to patient outcomes and experience of care (O8) and staff experiences(O7).

One further participant (coded as 17) had participated in another interdisciplinary project that included clinical and non-clinical staff who redesigned a pathway for people with a hip fracture. The team also succeeded in transcending silos and improved the quality of patient care. The percentage of patients undergoing surgery within 48 hours of presentation to the Emergency Department increased from 55% to 79% at three months, and to 85% at six months (Murphy et al., 2019). Staff satisfaction with the new pathway was recorded and showed overwhelming support for this new way of working.

The results of participants' Lean Six Sigma projects provides evidence supporting Outcomes O7 -O10 of the CMOc, 'aspects of organisational culture', (CMOc1) in their respective areas of practice. Posters summarising participants' projects can be found in Appendix 4.1.

5.2.3.4 Overview: Adjudication of Outcomes for CMOc1, 'Aspects of Organisational Culture'

Figure 5.5 CMOc1: Aspects of Organisational Culture - Adjudicated Outcomes



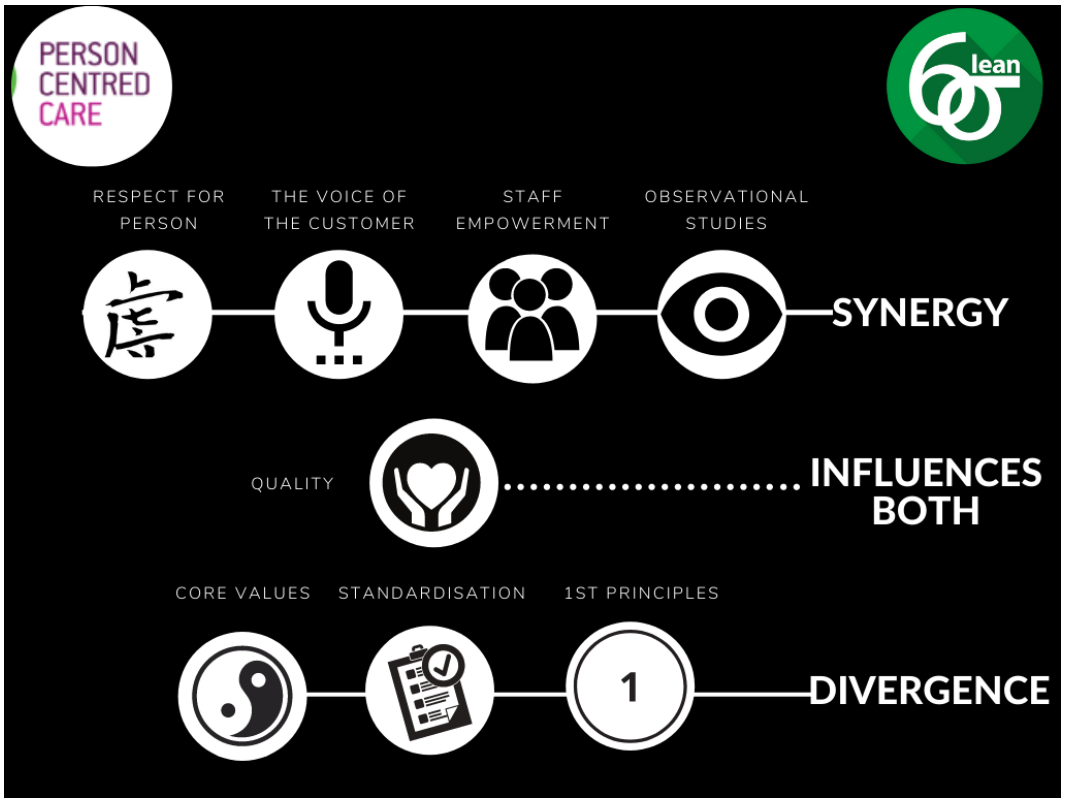
As shown again in figure 5.5, in the course of the adjudication process of the CMOc 'Lean Six Sigma and Staff', identified in the realist review, participants refuted one outcome (O2) and generated four new outcomes (O7, O8, O9, O10) for the embedded CMOc, 'aspects of organisational culture', (CMOc1). The new outcomes for CMOc1 were further supported by evidence from participants' Lean Six Sigma projects (Creed et al., 2019; Davies et al., 2019; Murphy et al., 2019; Teeling et al., 2019; Ryan et al., 2019 and Appendix 4.1).

There now follows discussion of how CMOc1, 'aspects of organisational culture', aligns to the synergies and divergences of Lean Six Sigma and person-centred care and cultures.

5.2.3.5 Aligning CMOc1 to the Synergies and Divergences of Lean Six Sigma and Person-centred Care and Cultures

In Chapter 2, the realist review identified synergies and divergences between Lean Six Sigma and person-centred care and cultures (Figure 5.6). In the final workshop, participants discussed and clarified how, in their experiences as Lean Six Sigma practitioners, CMOc1 might align to the synergies and divergences between both methodologies.

Figure 5.6 Synergies and Divergences between Lean Six Sigma and Person-centred Care and Cultures



Source: Taken from Teeling, Dewing and Baldie (2020, p.19)

Participants identified the following:

Synergies

1. Respect for Persons. Contextual factor C6 (communication is well organised and timely) and contextual factor C7 (staff are open to new ways of working) were seen as particularly relevant to this synergy, being respectful of staff. Mechanism M3 (management actively and visibly support and lead on improvement culture) and Mechanism M4 (the project charter is used to focus process improvement on both patient and staff outcomes) were judged to be staff-centred mechanisms at work in these contexts. Outcomes O7 (there is an explicit focus on staff experience in addition to that of patients) and Outcome O8 (increase in quality of care, and improved patient outcomes) were identified as particularly relevant outcomes for an organisational culture that respects people.

2. The Voice of the Customer (VOC). Participants felt that where improvement was not taking place in departmental silos (contextual factor C1) and there was an absence of scepticism toward process improvement (contextual factor C5) there was an opportunity to work collaboratively and inclusively. Contextual factor C6 (communication is well organised and timely) and contextual factor C7 (staff are open to new ways of working) were determined to be relevant contextual factors that enabled Mechanism M4 (the project charter is used to focus process improvement on both patient and staff outcomes), Mechanism M8 (recognition and use of support from the on-site service improvement team) and Mechanism M9 (Lean is promoted at the departmental level) to elicit the voice of staff and patients. Outcome O7 (there is an explicit focus on staff experience in addition to that of patients), Outcome O9 (culture change) and Outcome O10 (Lean Six Sigma transcends silos) were identified as outcomes congruent with seeking the 'Voice of the Customer'.

3. Staff Empowerment. Participants saw contextual factors C6 (communication is well organised and timely), C7 (staff are open to new ways of working), C8 (there is an integrative and distributed approach to Lean Six Sigma

deployment) and C9 (staff work in an organisation with competent Lean Six Sigma practitioners) as relevant in enabling the identified mechanisms M3, M4, M8 and M9 (management actively and visibly support and lead on improvement culture, the project charter is used to focus process improvement on both patient and staff outcomes, recognition and use of support from the on-site service improvement team, and Lean is promoted at the departmental level) to deliver the Outcomes O7 (there is an explicit focus on staff experience in addition to that of patients), O8 (increase in quality of care and patient outcomes), O9 (culture change) and O10 (Lean Six Sigma transcends silos) that were identified by participants as empowering staff.

4. Observational studies. Participants believed, in particular, that contextual factor C7 (staff are open to new ways of working)was relevant to staff in carrying out observational studies or Gemba, as this was a new practice for staff in some practice areas where improvement work was taking place. Participants experienced outcome O9 (culture change) and outcome 10 (Lean Six Sigma transcends silos) as relevant to observational studies. When adjudicating they had remarked how Gemba [observational studies] had enabled them to work outside their own practice areas, realising these outcomes.

Influencing Synergy and Divergence

1. Quality. Participants saw the absence of a culture of 'we've always done it this way' (contextual factor C1), improvement taking place only in departmental silos (contextual factor C2) and an absence of scepticism to process improvement (contextual factor C5) as facilitative of quality improvement. Contextual factors C6 (communication is well organised and timely), C7 (staff are open to new ways of working), C8 (integrative and distributed approach to Lean Six Sigma deployment) and C9 (staff work in an organisation with competent Lean Six Sigma practitioners) as relevant enabling contextual factors for quality. All mechanisms M3, M4, M8 and M9 (management

actively and visibly support and lead on improvement culture, the project charter is used to focus process improvement on both patient and staff outcomes, recognition and use of support from the on-site service improvement team, and Lean is promoted at the departmental level) were also discerned as important mechanisms to enable quality outcomes. All outcomes, O7 (there is an explicit focus on staff experience in addition to that of patients), O8 (increase in quality of care and patient outcomes), O9 (culture change) and O10 (Lean Six Sigma transcends silos) were seen as important in understanding the difference in perception between quality as measurement of outcomes or a metric, and a quality patient and staff experience.

Divergence

1. Core Values. Participants felt that contextual factors C6 (communication is well organised and timely) and C7 (staff are open to new ways of working) were particularly relevant to the core values of valuing people and understanding people's values as opposed to a perception of the value inherent in the actual process improvement. Mechanisms M3, M4 and M8 (management actively and visibly support and lead on improvement culture, the project charter is used to focus process improvement on both patient and staff outcomes, and recognition and use of support from the on-site service improvement team) were seen as mechanisms that showed an appreciation for staff and consequently 'valued' their values and beliefs. Outcome O7 (there is an explicit focus on staff experience in addition to that of patients) was seen as particularly relevant in this regard.

2. Standardisation was not assigned to any particular divergence or synergy evident within CMOc1.

3. First Principles. Contextual factors C8 (integrative and distributed approach to Lean Six Sigma deployment) and C9 (staff work in an organisation with competent Lean Six Sigma practitioners) were considered important in

understanding what Lean and Six Sigma mean and how they can relate to person-centred care. Mechanism M8 (recognition and use of support from the on-site Lean team) was seen as a major mechanism to enable staff engagement with, and understanding of, both Lean Six Sigma and person-centred care methodologies. All outcomes O7 (there is an explicit focus on staff experience in addition to that of patients), O8 (increase in quality of care and patient outcomes), O9 (culture change) and O10 (Lean Six Sigma transcends silos) were identified as relevant when the first principles of Lean Six Sigma and person-centred care, and the divergence between them, were clearly understood.

5.3 Conclusion

This chapter presented the contextual factors (C), mechanisms (M) and outcomes (O) that were identified by research participants through their adjudication of CMOc1, 'aspects of organisational culture'. At the study site, Lean Six Sigma practitioners had experienced Lean Six Sigma as an integrative and distributive approach (C) that was well communicated to staff (C) who were open to new ways of working (C). The study site also had a high number of competent Lean Six Sigma practitioners (C). Management within the hospital were visibly active in their support of Lean Six Sigma students and practitioners (M) who used a project charter template to focus their improvement work (M). The promotion of Lean Six Sigma at departmental level (M) ensured it was understood within specific practice areas and staff were aware of, and used, the support available from the on-site service improvement team (M). In the organisation, staff engagement with Lean Six Sigma led to a focus on staff experience in addition to that of patients (O) and an increase in the quality of patient care and outcomes (O). Lean Six Sigma had also led to a recognised change in the organisational culture (O) and to an ability for staff to transcend their traditional practice area silos (O). In situations where Lean Six Sigma practitioners had in the past encountered a reaction of 'we've always done it this way' (C), or 'we've tried that before and it didn't work' (C) or where improvement took place in silos (C), Lean Six Sigma practitioners indicated how that had adversely influenced their engagement

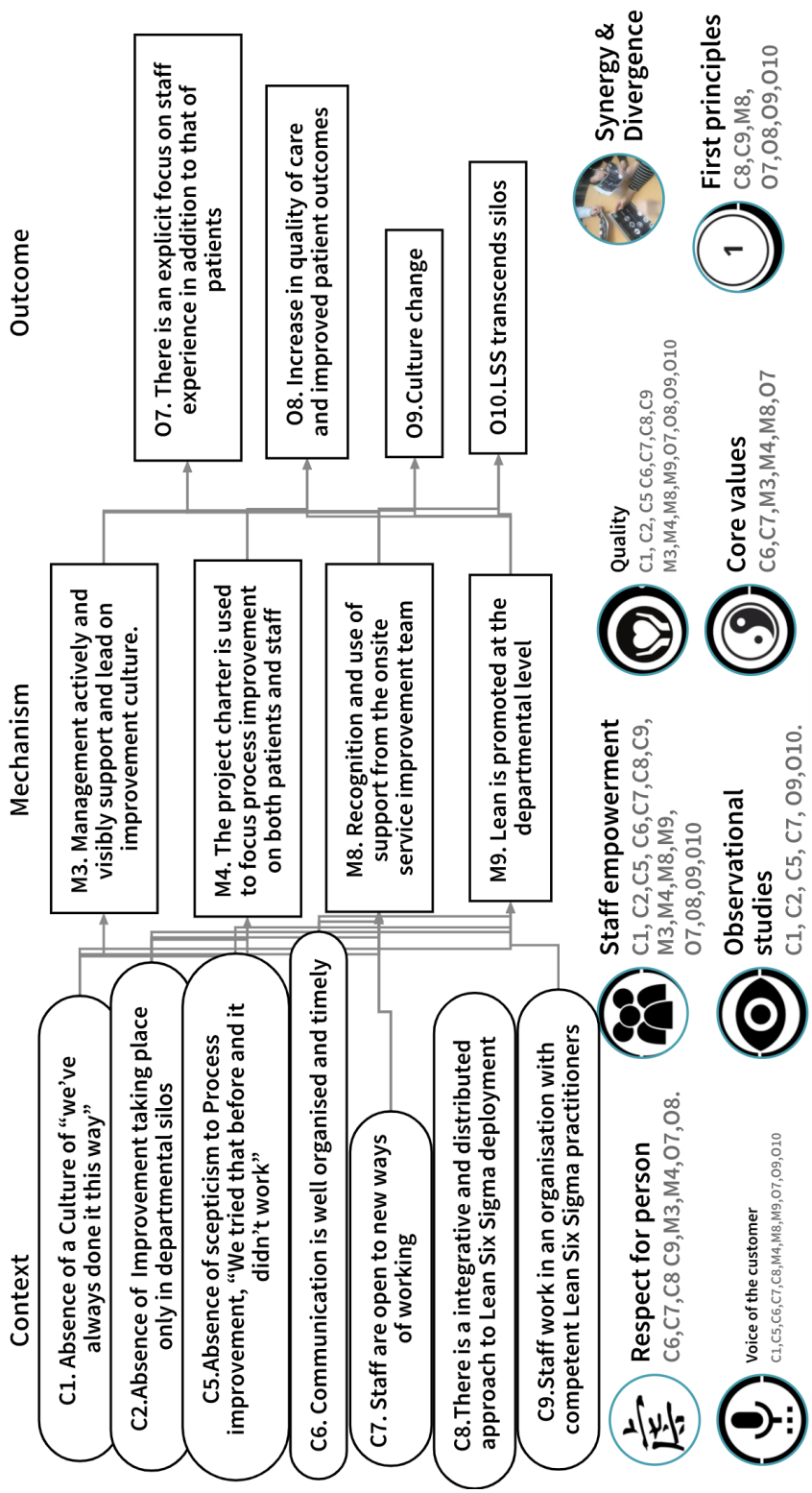
with the Lean Six Sigma education and training programme, and that the anticipated outcomes (O) were not achieved.

A series of diagrams illustrating this fully elaborated, incremental development of CMOc1 through all stages of participant adjudication, including its mapping to the synergies and divergences between the Lean Six Sigma and person-centred care methodologies is presented in Appendix 5.1. The final adjudicated CMOc1, reflecting the results of all stages of adjudication is shown in figure 5.7. The programme theory of this research is that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures (chapters one and three) if delivered through the intervention of the UCD Lean Six Sigma education and training programme. The visual representation of the CMOc, 'aspects of organisational culture', (figure 5.7) indicates that, in relation to the intervention of the UCD Lean Six Sigma education and training programme, participants were able to identify:

- contextual factors (C) that facilitated or hindered their Lean Six Sigma practice work.
- the outcomes (O) that emerged because of the action of underlying mechanisms (M) that they identified as active when the contextual factors (C) were present.
- the synergy, influence and divergence between their Lean Six Sigma practice and person-centred care and cultures.

In now proceed to present the findings relating to the adjudication of CMOc2 'the organisation's receptivity to Lean Six Sigma'.

5.7 Adjudicated CMOc1 Mapped to Synergy, Influencer and Divergence

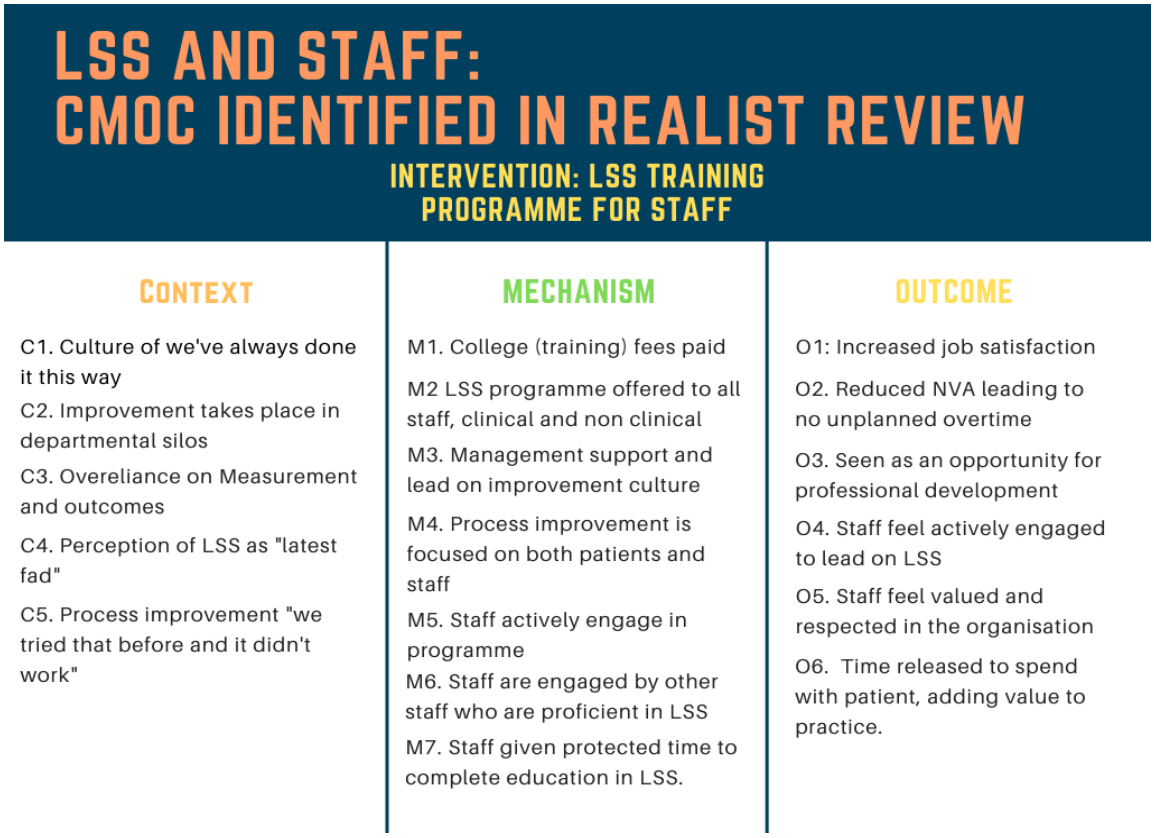


Chapter 6: CMOc2, The Organisation's Receptivity to Lean Six Sigma

6.1 Introduction

This chapter again begins with reference to the CMOc, 'Lean Six Sigma and Staff', generated from the realist review (chapter 2) in which five contexts, seven mechanisms and six outcomes were identified (figure 6.1).

Figure 6.1 CMOc 'Lean Six Sigma and Staff' from the Realist Review



Participants reviewed, refined and developed this CMOc through an adjudication process comprising an initial series of workshops, twenty individual interviews and a final workshop series, as outlined in figure 4.15. This refinement led to the development of three focused or embedded CMOcs, the second of which 'the organisation's receptivity to Lean Six Sigma' is discussed in this chapter.

As well as confirming, refuting and refining certain of the contexts, mechanisms and outcomes shown in figure 6.1, participants identified new ones at various stages of the adjudication process (figure 4.15). Congruent with realist evaluation methodology, confirmations, refutations or refinements of the programme theory that facilitate or hinder the effectiveness of the intervention to deliver anticipated outcomes are presented, supported by illustrative quotations from participants that are representative of their collective view (Pawson & Tilley, 1997; Dobson & Fitzgerald, 2005).

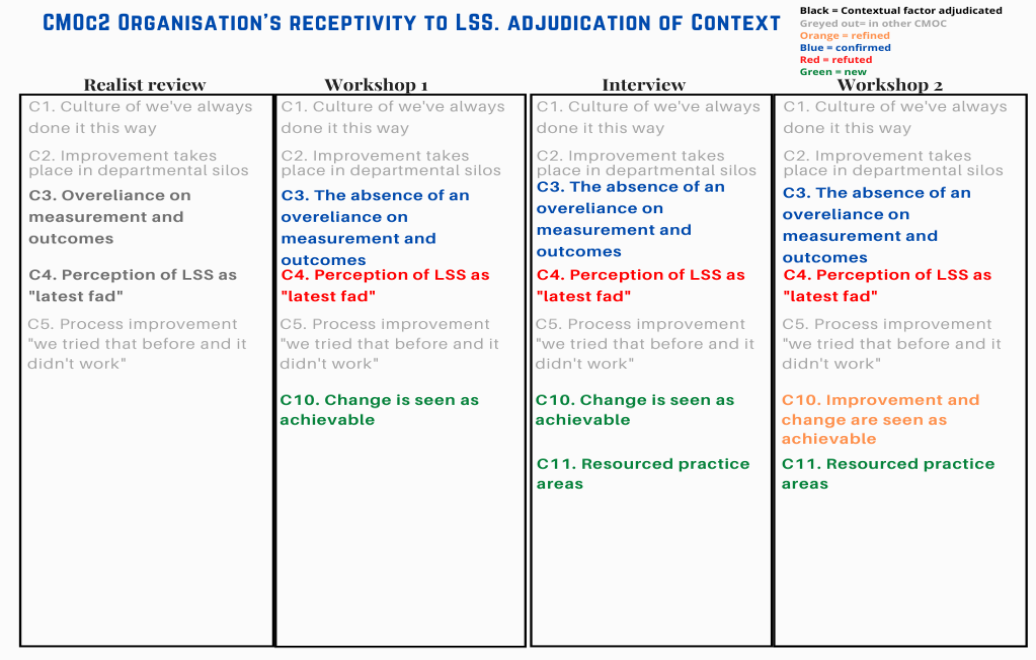
The second focused CMOc, 'the organisation's receptivity to Lean Six Sigma' is now discussed.

6.2 CMOc2: The Organisation's Receptivity to Lean Six Sigma

This section begins by presenting participants' adjudication of contexts, mechanisms and outcomes for CMOc2. The section concludes by considering the synergies and divergences of Lean Six Sigma and person-centred care within CMOc2. The adjudication of contexts is discussed first.

6.2.1 Adjudication of Contexts for CMOc2

Figure 6.2 CMOc2: The Organisation's Receptivity to Lean Six Sigma - Adjudicated Contexts.



As shown in figure 6.2, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff' identified in the realist review, participants confirmed one context (C3), refuted another (C4) and generated two new contexts (C10, C11) for the embedded CMOc, 'the organisation's receptivity to Lean Six Sigma', (CMOc2). The confirmed and refuted contexts are discussed first, followed by the two new ones.

6.2.1.1 Adjudication of Contexts for CMOc2: Confirmation and Refutation

For the CMOc, 'Lean Six Sigma and Staff', two contextual factors or features were identified that influenced how staff interacted with Lean Six Sigma deployment in their organisation (figure 6.2):

- Overreliance on measurement and outcomes (C3)
- Perception of Lean Six Sigma as latest fad (C4)

The adjudication of each of these contextual factors for CMOc2 is now discussed in turn.

C3: Overreliance on measurement and outcomes - confirmation

Participants acknowledged that there was a perception among some colleagues that Lean Six Sigma was overreliant on measurement and outcomes. Apart from the measurement for improvement inherent in Lean Six Sigma interventions, participants noted that they and their colleagues experienced many other types of Key Performance Outcomes (KPIs) and metrics in their daily practice:

> so many metrics internally and externally…nursing metrics, Trolleygar, HIQA [Health Information and Quality Authority], JCI [Joint Commission International] accreditation.
>
> P4, Clinical Trials Manager, Workshop 1.

Participants felt that staff might perceive the volume of KPIs and metrics that they were required to work with as onerous and unnecessary:

> can be a view of them [KPIs and metrics] as being additional workload by some [staff]…they query the volume of measures they have to collect.
>
> P10, Practice Development Nurse, Workshop 1.

The importance of discussing the rationale for measurement with staff was highlighted by the same participant:

> [staff] should have the specific metrics relating to their work explained to them…allow time for discussion.

P10, Practice Development Nurse, Workshop 1.

However, participants themselves experienced measuring improvement in Lean Six Sigma interventions differently, as not overreliant on measurement and outcomes, but with a strong focus on staff and patient experience (Voice of the Customer):

> [the] metrics and KPIs we use in [Lean Six Sigma] projects are agreed with the process owners [local staff involved in the project work] so that they have input into their design and implementation.
>
> P 19, Assistant Director of Nursing, Workshop 1.

> we [Lean Six Sigma practitioners] understand that there is a focus on staff experience and the use of measurement is not meant to put pressure on staff.
>
> P8, Administration Team Manager, Workshop 1.

It was agreed that, despite their own experience as Lean Six Sigma practitioners, it was important to facilitate staff in the use of measurement for improvement:

> [I] think with clinicians in particular and HSCPs [Health and Social Care Professions] as well, it's seen as something that they were never trained in. That's [training in measurement for improvement] something we do as part of our [Lean Six Sigma] training.
>
> P12, Physiotherapist, Workshop 1.

Where staff were educated, involved and understood the rationale for metrics to measure improvement, they endorsed their use:

> …nursing metrics are very well received because they [nurses] understand them, the need for them, and see the impact of measuring patient outcomes.
>
> P10, Practice Development Nurse, Workshop 1.

> KPIs and metrics are not a bad thing if they are necessary, developed with staff and are used appropriately and judiciously.
>
> P15, Pharmacist, Workshop 1.

> we [participant and practice area colleagues] use KPIs appropriately and in a positive way, it's a very good way for us to know how we are performing.

P5, Senior Medical Scientist, Workshop 1.

One participant summed it up succinctly:

> accurate measurement…metrics and KPIs developed with the staff are excellent…they [staff] feel their experience counts, they are heard, and they understand the metrics…had a hand in their design.
>
> P13, Project Manager, Workshop 1.

As part of their Lean Six Sigma education and training, participants were introduced to person-centred principles and the need to focus on experiences of care and not just its outcomes. Participants experienced patient as well as staff involvement in designing measures for improvement with this focus on their experiences of care:

> we involved patients who had [implantable cardiac] devices… in education sessions for other patients who were considering using them…asking them [patients] how to measure the success of the device and what their own experiences were.
>
> P9, Clinical Nurse Specialist, Workshop 1.

> patients and their relatives who had dysphagia…involved in the design of a new pathway to ensure that any patient presenting as an emergency had their 'swallow' status identified early, so that they were not left without food or drink unnecessarily.
>
> P16, Speech and Language Therapist, Workshop 1.

In the first series of workshops, participants acknowledged that some staff could find KPIs, metrics and measurement as onerous and that they might feel that there was an overreliance on their use. However, participants' own experiences were that Lean Six Sigma interventions took a more holistic approach, sought the Voice of the Customer, involved both patients and staff and addressed their experiences of care. Additionally, they felt that the continued use of Lean Six Sigma to involve staff in understanding current KPIs and metrics, and developing new ones was a proactive approach by the organisation to embedding improvement measures.

Participants therefore confirmed that overreliance on measurement and outcomes was a contextual factor that they recognised, and where it was present it would hinder how they and other colleagues engaged with Lean Six Sigma. However, they also noted

that where this overreliance in measurement and outcomes was absent, and measurement focused on both patient and staff experiences of care in addition to its outcomes, it facilitated how they and other colleagues engaged with Lean Six Sigma.

C4: Perception of Lean Six Sigma as 'latest fad' – refutation

Participants were resolute in their adjudication of this contextual factor, with all saying that they had not experienced it. This was based on their own experiences of working on Lean Six Sigma projects:

> [I] know that Lean is not just the latest thing, it's here to stay, and I've been at it for 5 years now!
>
> P5, Senior Medical Scientist, Workshop 1.

> I don't think they[staff] think Lean is just another 'new' thing, and it's not perceived as…a new fad or flavour of the month.
>
> P15, Pharmacist, Workshop 1.

> [Lean Six Sigma] has been around so long now that it's very much part of the language here…wouldn't be perceived as a 'fad'.
>
> P16, Speech and Language Therapist, Workshop 1.

Participants therefore refuted the contextual factor, "perception of Lean Six Sigma as 'latest fad'".

Summary

At the end of the adjudication process, one contextual factor had been confirmed as being influential in how people engaged locally with Lean Six Sigma:

- Overreliance on measurement and outcomes (C3)

It was where this contextual factor was absent that positive engagement with the intervention was experienced. It is therefore best expressed and situated in the CMOc as:

- The absence of an overreliance on measurement and outcomes

Additionally, one contextual factor had been refuted:

- Perception of Lean Six Sigma as the 'latest fad' (C6)

6.2.1.2 Adjudication of contexts for CMOc2: new contexts

In the adjudication process, two new contextual factors for CMOc2 were identified:

- Improvement and change are seen as achievable (C12).
- Resourced practice areas (C13)

Each is now discussed in turn.

C10: Improvement and change are seen as achievable

Participants had good experiences of working with colleagues who, although busy in their substantive posts, were willing to engage with Lean Six Sigma improvement:

> [staff] know it's [Lean Six Sigma project work] aiming to get results…although they are busy, they do engage.
>
> P4, Clinical Trials Manager, Workshop 1.

> there is sometimes a feeling that it [Lean Six Sigma] is additional work, but they [staff] are always keen to participate and help with the [Lean Six Sigma] project work.
>
> P1, Data Manager, Workshop 1.

Participants felt one factor that contributed to this willingness by staff to engage was the fact that they had visibility of the results from ongoing Lean Six Sigma projects:

> results from the Green and Black Belts are disseminated in the CEO newsletter and at our symposium…workshops and poster displays, so they [staff] can see that change does happen.
>
> P7, Service Improvement Lead, Workshop 1.

Participants also felt that many staff saw change as achievable because they had been involved in projects within their practice areas:

> a good number of people who haven't trained in Lean Six Sigma but who have had a Lean Six Sigma project take place in their unit…have been involved in the process.
>
> P19, Assistant Director of Nursing, Workshop 1.

> very much a 'yes we can' attitude among staff when it comes to VSA [Value Stream Analysis] or any type of improvement work really…it's [Lean Six Sigma] been running in the hospital so long now that it has a proven track record.
>
> P13, Project Manager, Workshop 1.

Participants therefore generated an initial contextual factor of 'change is seen as achievable'.

In the interviews this new contextual factor was again adjudicated, and participants talked about both change and improvement as different things:

> change and improvement are two different things…need to be careful that we don't mistake one for the other.
>
> P16, Speech and Language Therapist, Interview.

> change is changing the way we do it, but sometimes you just want to improve the way you do it currently, so I would say we [Lean Six Sigma practitioners] do both.
>
> P3, Assistant Director of Nursing, Interview.

These thoughts on the difference between change and improvement and what Lean Six Sigma practitioners seek to achieve were discussed again in the second series of workshops. Here there was agreement that both 'change' and 'improvement' should be captured in the new contextual factor. Participants felt that as improvement in the current way of doing things often precedes change in the way that we do them, the contextual factor should be refined to 'improvement and change are seen as achievable'.

C11: Resourced practice areas

As Lean Six Sigma interventions take place both within and across practice areas, participants felt that a contextual factor relating to the availability of resources in the practice areas was an important consideration when looking at staff's willingness to engage.

Access to tangible resources was considered important:

> sometimes you're waiting at the [ward] station and you can't get to a computer …you can't get to the phone, because there are one or two phones and one computer and a queue of staff waiting to use them.
>
> P12, Physiotherapist, Interview.

> space can be an issue…space to see a patient. We've had nurses and doctors available but no space to see them, so it's an important consideration.
>
> P9, Clinical Nurse Specialist, Interview.

The availability of facilities and spaces to meet, consult, design and plan process improvements in practice areas was another important condition that enabled Lean Six Sigma practice:

> we do a lot of process mapping, so we need a lot of wall space… several conference and meeting rooms within the directorate where we hold our Lean meetings.
>
> P20, Operations Manager, Interview.

> the physio[therapy] meeting room is available for brainstorming sessions with stakeholders…really important to have a separate space to work.
>
> P12, Physiotherapist, Interview.

> [I] held a lot of workshops for my Black Belt so I needed a physical space for these…conference room on level zero or the transformation conference room were available for my use.
>
> P 15, Pharmacist, Interview.

> The quiet space available [within the practice area] was key in carrying out interviews with the ED [Emergency Department] team during our project.

P2, Operations Manager, Interview.

Human resources were also considered important:

> trying to make a process improvement in a short-staffed unit can be hard work…people have to be in the head space.
>
> P11, Discharge Coordinator, Interview.

> we recognise benefits that everybody individually has achieved with Lean Six Sigma in our department, and people are very much willing to do it [Lean Six Sigma] even though a recurring factor is our resources are becoming more limited.
>
> P5, Senior Medical Scientist, Interview.

And sometimes both tangible and human resources were an issue:

> within a [Lean Six Sigma] project when you've done all the background work…might need IT [Information Technology] support…not just the equipment but also the software programmer.
>
> P7, Service Improvement Lead, Interview.

These comments from the interviews were reviewed and adjudicated in the second series of workshops. Participants agreed that both tangible and intangible [human] resources within practice areas were important contextual factors to be considered when undertaking Lean Six Sigma work. Attention to these factors was again discussed:

> I was involved in a project on a day surgery unit. Getting the VOC [voice of the customer] by talking to nursing staff showed they were unhappy with their units lack of identity…the only department without a specific uniform …no lockers. This was fed back to the Director of Nursing, and both new uniforms and lockers were put in place before we began our Lean Six Sigma work.
>
> P8, Administration Team Manager, Workshop 2.

> you can still try to make a process improvement in an area where there are resource issues …and you might succeed, but it's far easier when resources are in place and staff will engage.
>
> P20, Operations Manager, Workshop 2.

Participants therefore developed a contextual factor to reflect their experience of what would facilitate a Lean Six Sigma intervention: ‘resourced practice areas’.

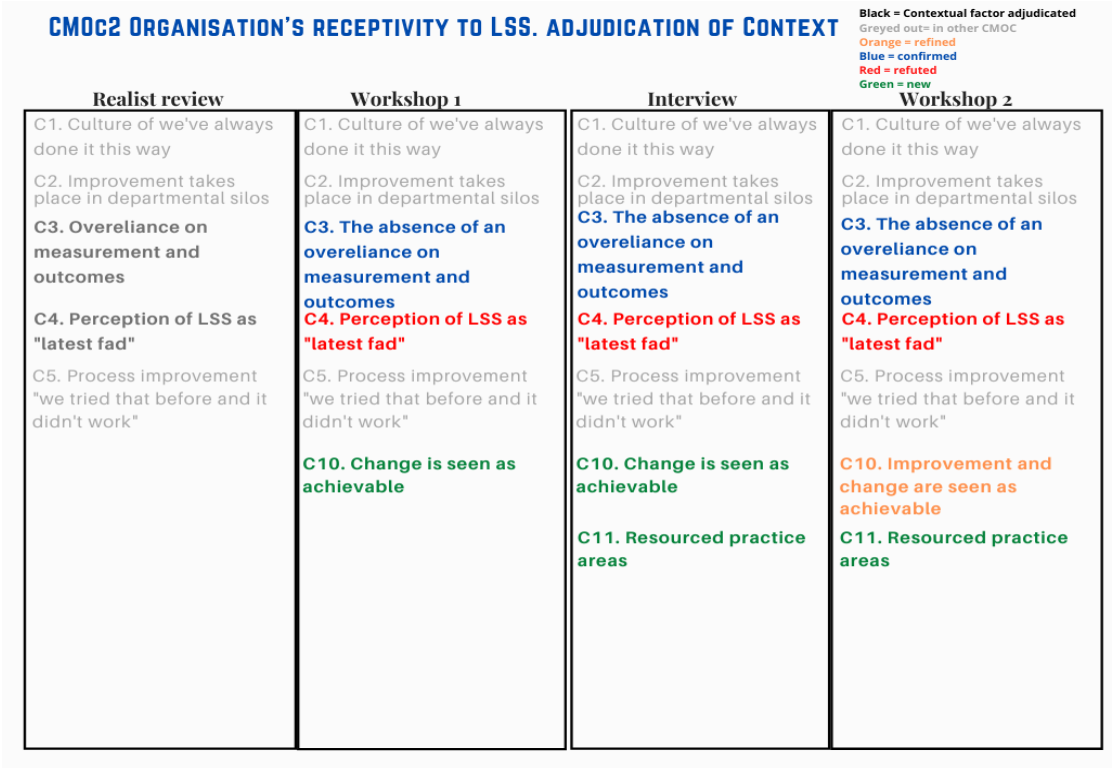
Summary

At the end of the adjudication process, two new contextual factors influencing how people engage with Lean Six Sigma were proposed:

- Improvement and change are seen as achievable (C11)
- Resourced practice areas (C12)

6.2.1.3 Overview: Adjudication of Contexts for CMOc2, ‘The Organisation’s Receptivity to Lean Six Sigma’.

Figure 6.2 CMOc2: Organisation’s Receptivity to Lean Six Sigma - Adjudicated Contexts.



As shown again in figure 6.2, by the end of the adjudication process, one contextual factor had been confirmed:

- The absence of an overreliance on measurement and outcomes

Another contextual factor had been refuted:

- Perception of Lean Six Sigma as the 'latest fad' (C4)

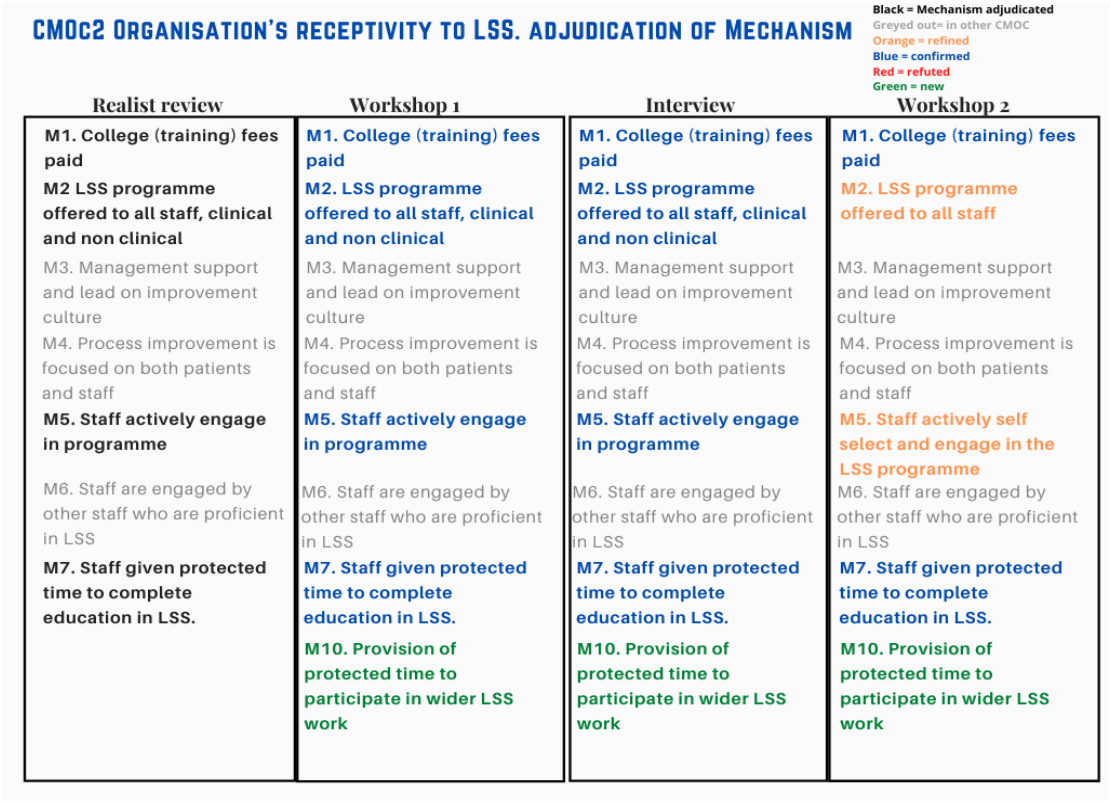
And two new contextual factors were identified:

- Improvement and change are seen as achievable (C10)
- Resourced practice areas (C11)

The findings of participants' adjudication of mechanisms for CMOc2, 'the organisation's receptivity to Lean Six Sigma' are now presented.

6.2.2 Adjudication of Mechanisms for CMOc2 'The Organisation's Receptivity to Lean Six Sigma'.

Figure 6.3 CMOc2: The Organisation's Receptivity to Lean Six Sigma - Adjudicated Mechanisms



As shown in figure 6.3, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants confirmed two mechanisms (M1 and M7), refined two (M2 and M5) and generated one new mechanism (M10) for the embedded CMOc, 'the organisation's receptivity to Lean Six Sigma', (CMOc2). The two confirmed and two refined mechanisms are discussed first, followed by the two new mechanisms.

6.2.2.1 Adjudication of Mechanisms for CMOc1: Confirmation and Refinement

Participants adjudicated the five mechanisms from the realist review of the literature and identified four as resonating particularly with CMOc2, 'the organisation's receptivity to Lean Six Sigma', (figure 6.3):

- College (training) fees paid (M1)
- Lean Six Sigma programme offered to all staff, clinical and non-clinical (M2)
- Staff actively engage in programme (M5)
- Staff given protected time to complete education in Lean Six Sigma (M7)

The adjudication of each of these mechanisms is now discussed in turn.

M1: College (training fees) paid

Participant's felt that funding for training was an important mechanism that had both encouraged and enabled them to engage with the intervention of the Lean Six Sigma education and training programme:

> staff get White Belts [fundamentals of lean training] for free and have been funded on Green [professional certificate] and Black [graduate diploma], hugely important.
>
> P5, Senior Medical Scientist, Workshop 1.

> [the] fact that I didn't have to worry about fees…there for me if I wanted to take it up…enabled me to access and participate in the [Lean Six Sigma] training.
>
> P20, Operations Manager, Workshop 1.

> in particular funding support would have been a big instrument in undertaking Lean training, particularly for the Black Belt.
>
> P4, Clinical Trials Manager, Workshop 1.

In the first series of workshops, the participants therefore confirmed the existence of a mechanism of 'College (training fees) paid'. They confirmed the programme theory assumption that in practice areas where this mechanism is present it facilitates their engagement with Lean Six Sigma work. This mechanism was further discussed in the interviews and the importance of funding to individuals was reiterated.

> the biggest influencing factor in terms of supporting her [a staff member] to go to UCD was the availability of the funding which was really important.
>
> P16, Speech and Language Therapist, Interview.

> [I] wouldn't have been able to do the Black Belt if I hadn't been sponsored. I mean I would like to have done it… from a financial point of view, with family cost commitments, it would never have been possible.
>
> P9, Clinical Nurse Specialist, Interview.

The results from interview adjudication were fed back in the second workshop series; however, participants felt that the mechanism adequately represented their views and experiences and no further refinement was required.

M2: Lean Six Sigma programme offered to all staff, clinical and non-clinical

Participants highlighted the presence of this mechanism as important for the organisation as it was seen as giving equitable and fair access to Lean Six Sigma education and training:

> enables everyone in the hospital to access it [Lean Six Sigma], regardless of discipline or experience…painters, electricians, doctors, nurses, everyone has access.
>
> P5, Senior Medical Scientist, Workshop 1.

> a new way of working…giving everyone a voice and input into problem solving…generating solutions.
>
> P15, Pharmacist, Workshop 1.

Participants felt that it enabled staff to participate in process improvement and have their opinions heard:

> allows people [staff] to engage on an equal level…more likely to get a more realistic spread of feedback as to how things are working in the hospital…everyone's voice counts.
>
> P16, Speech and Language Therapist, Workshop 1.

It was also a change in the way education and training programmes had traditionally been offered to staff:

> [the] traditional approach…train all the NCHDs [Non-Consultant Hospital Doctors], train all the nurses, focus on the clinicians…a fresh approach.

P4, Clinical Trials Manager, Workshop 1.

In the first series of workshops, the participants confirmed the existence of a mechanism of 'Lean Six Sigma programme offered to all staff, clinical and non-clinical'. They confirmed the programme theory assumption that in practice areas where this mechanism is present it facilitates their engagement with Lean Six Sigma work. This mechanism was adjudicated again in the individual interviews, and in the second workshop series was refined further:

> [I] talked in my interview about the clinical and non-clinical tags…seems to suggest there is still a difference between them [clinical and non-clinical staff] whereas the focus is on every staff member having the same access.
>
> P19, Assistant Director of Nursing, Workshop 2.

> agree that the clinical and non- clinical still suggests a divide…not sure I like the differentiation.
>
> P8, Administration Team Manager, Workshop 2.

This led to discussion of the need for the clinical and non-clinical delineation:

> clinical and non-clinical wording implies the non-clinical roles aren't as important when we all know they are. Can we change this to simply state staff or employees?
>
> P 17, Data Coordination Lead, Workshop 2.

During these discussions it was also noted that other mechanisms that participants had refined, confirmed, refuted or generated contained the word 'staff' and didn't specify clinical or non-clinical. Participants therefore refined the mechanism to 'Lean Six Sigma programme offered to all staff'.

M5: Staff actively engage in programme

This mechanism identified in the realist review refers to staff self-selecting for the intervention of the Lean Six Sigma education and training programme as opposed to

being sent on it by their line managers. Participants had independently chosen to undertake Lean Six Sigma education and training:

> [I] know colleagues who were sent on [Lean Six Sigma] training in [another organisation] and they didn't even know what it was all about. Fortunately, that's not the [hospital] experience.
>
> P2, Operations Manager, Workshop 1.

> [you] have an improvement project idea, discuss it with your manager to get their support and then apply…[it's] very much a self-motivated application process.
>
> P7, Service Improvement Lead, Workshop 1.

> [when] you apply for the Green Belt you have to have an improvement project in mind and have completed a project charter…you are the one with the ideas.
>
> P3, Assistant Director of Nursing, Workshop 1.

Participants self-selected because they wanted to undertake Lean Six Sigma education and training:

> …something that I really wanted to do, and I applied for the very first programme.
>
> P8, Administration Team Manager, Workshop 1.

> [I] had a specific project I wanted to work on so applied for the Green Belt so I could work on this.
>
> P13, Project Manager, Workshop 1.

In the first series of workshops, the participants confirmed the existence of a mechanism of 'staff actively engage in programme'. They confirmed the programme theory assumption that in practice areas where this mechanism is present it facilitates their engagement with Lean Six Sigma work. There was no refining of this mechanism in the interviews; however, in the second series of workshops, it was again discussed by participants. Here participants expressed the view that the mechanism as stated did not capture the discussion on self-selection that had taken place in workshop one:

> …the volunteering for it [Lean Six Sigma education and training programme] was a really important part of the discussion and is missing.
>
> P 17, Data Coordination Lead, Workshop 2.

> putting yourself forward is a real reason for engaging with it [Lean Six Sigma education and training programme] that is not represented in this [the mechanism] as stands.
>
> P1, Data Manager, Workshop 2.

All participants had self-selected for the Lean Six Sigma education and training programme and had not experienced any colleagues within the organisation who had been sent on the programme. Participants also felt that to give consistency to the mechanisms that 'the programme' should be explicitly stated as 'the Lean Six Sigma programme'. Following discussion, the participants therefore refined the contextual factor of 'staff actively engage in programme' to 'staff actively self-select and engage in the Lean Six Sigma programme'.

M7: Staff given protected time to complete education in Lean Six Sigma

Participants saw synergy and overlap between this mechanism and mechanism M1 'college (training fees) paid'. Both relate to enabling staff to complete the Lean Six Sigma education and training programme with the University:

> time I was given by my manager to complete the programme was really important. I don't think I could have taken the programme if I had had to use annual leave, even with my fees paid. Fees and study days go hand in hand in my opinion.
>
> P5, Senior Medical Scientist, Workshop 1.

There was agreement on the importance of the protected time, predominantly for personal reasons:

> couldn't afford to use annual leave to do the programme – try telling the family that holidays are cancelled because Mammy can't go.
>
> P7, Service Improvement Lead, Workshop 1.

> in 2014 we were getting married…needed every day for the planning and execution, the event and the honeymoon. The study time I got to do the Green Belt [professional certificate] was invaluable.
>
> P6, Discharge Coordinator, Workshop 1

> If you don't get the time off…study leave, it's a massive chunk that's going to be gone out of your annual leave and that's a personal and maybe a family toll as well.
>
> P15, Pharmacist, Workshop 1.

In the first series of workshops, the participants confirmed the existence of a mechanism of 'staff given protected time to complete education in Lean Six Sigma'. They confirmed the programme theory assumption that in practice areas where this mechanism is present it facilitates their engagement with Lean Six Sigma work. Although reviewed and discussed through the interviews and the second series of workshops, participants felt that the mechanism adequately represented their views and experiences, and no further refinement was required.

Summary

At the end of the adjudication process (figure 6.3), two mechanisms were confirmed:

- College (training fees) paid (M1)
- Staff given protected time to complete education in Lean Six Sigma (M7)

Two mechanisms were refined from:

- Lean Six Sigma programme offered to all staff, clinical and non-clinical (M2)
- Staff actively engage in programme (M5)

to:

- Lean Six Sigma programme offered to all staff (M2)
- Staff actively self-select and engage in the Lean Six Sigma programme (M5)

6.2.2.2 Adjudication of Mechanisms for CMOc2: New Mechanisms

In the adjudication process, one new mechanism for CMOc2 was identified as follows:

- Provision of protected time to participate in further Lean Six Sigma work (M10)

This is now discussed.

M10: Provision of protected time to participate in wider Lean Six Sigma work

Participants had confirmed mechanism M7, 'staff given protected time to complete education in Lean Six Sigma'. They felt that this mechanism did not capture the time spent carrying out Lean Six Sigma work after the education programme. In effect, although participants confirmed that they practiced Lean Six Sigma within their specific practice areas, they felt it was harder to contribute to whole-hospital Lean Six Sigma projects:

> [I] find that if I'm involved in more hospital-wide Lean Six Sigma projects, the bigger more collaborative work, then my own work is still waiting for me in my own department when I go back there.
>
> P1, Data Manager, Workshop 1.

Other participants also felt that participation in whole hospital work could be hard to complete due to practice area commitments:

> when I involve in work outside the unit then I either face a backlog of my own work or ask colleagues to cover me. That's ok now and again, but it's not ok as the rule of thumb.
>
> P9, Clinical Nurse Specialist, Workshop 1.

Participants felt that mechanism M7, 'staff given protected time to complete education in Lean Six Sigma' required a complimentary mechanism which spoke to the provision of staff to cover to work in cross-functional Lean Six Sigma teams outside their practice areas:

> the system-wide Lean Six Sigma does require time, particularly in the initial stages of data collection and measurement and that requires a lot of time…can end up doing it in your own time.
>
> P5, Senior Medical Scientist, Workshop 1.

> protected time for the college work needs to extend to the big project work …enable people to more fully engage with further Lean work.
>
> P20, Operations Manager, Workshop 1.

Participants therefore generated and confirmed the new mechanism, 'provision of protected time to participate in wider Lean Six Sigma work'. Although reviewed and discussed during the interviews and second workshop series, participants felt that the mechanism adequately represented their views and experiences, and no further refinement was required.

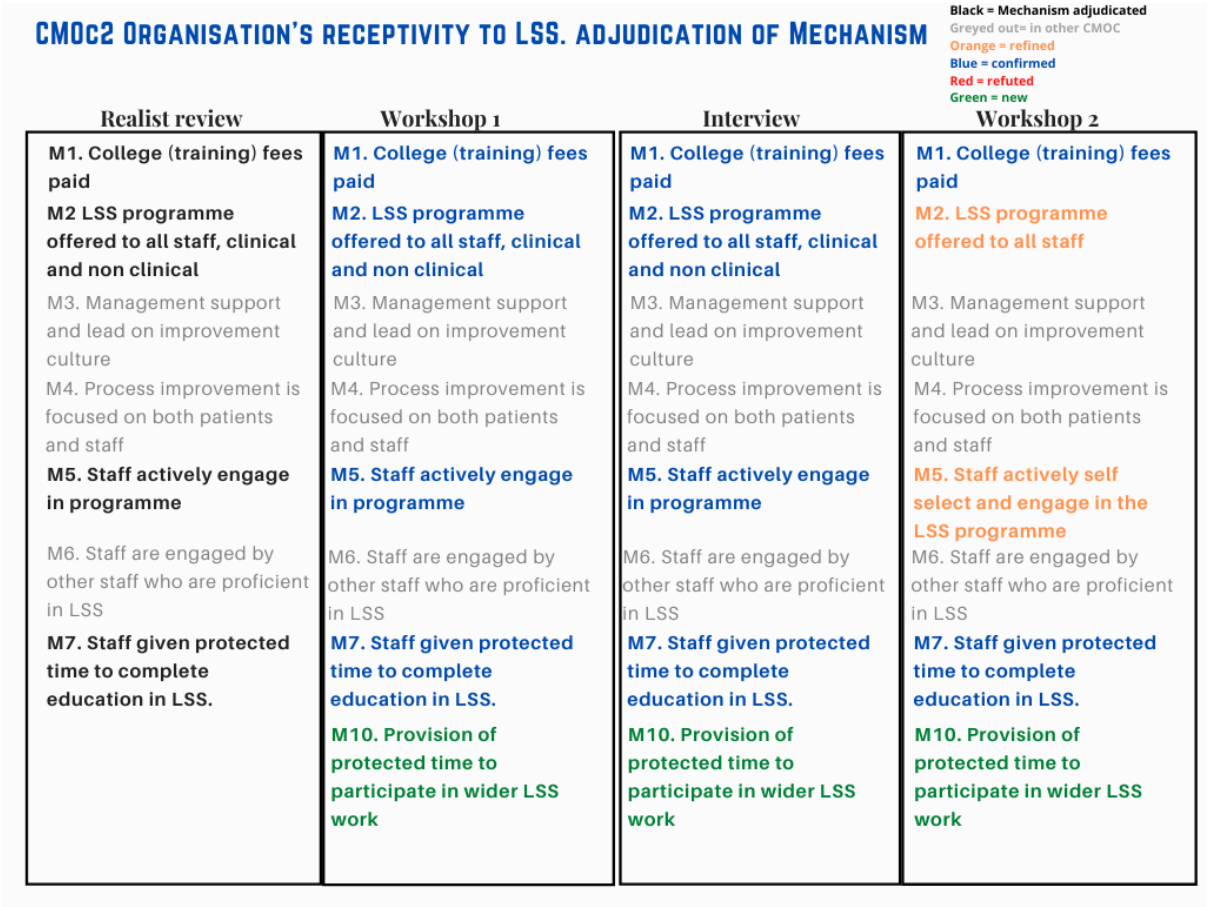
Summary

One new mechanism was identified in the adjudication process (figure 6.3):

- 'Provision of protected time to participate in wider Lean Six Sigma work' (M10)

6.2.2.3 Overview: Adjudication of Mechanisms for CMOc2 'The Organisation's Receptivity to Lean Six Sigma'

Figure 6.3 CMOc2: The Organisation's Receptivity to Lean Six Sigma - Adjudicated Mechanisms



As shown again in figure 6.3, at the conclusion of the adjudication process, two mechanisms had been confirmed:

- College (training fees) paid (M1)
- Staff given protected time to complete education in Lean Six Sigma (M7)

Two mechanisms been refined from:

- Lean Six Sigma programme offered to all staff, clinical and non-clinical (M2)
- Staff actively engage in programme (M5)

to:

- Lean Six Sigma programme offered to all staff (M2)
- Staff actively self-select and engage in the Lean Six Sigma programme (M5)

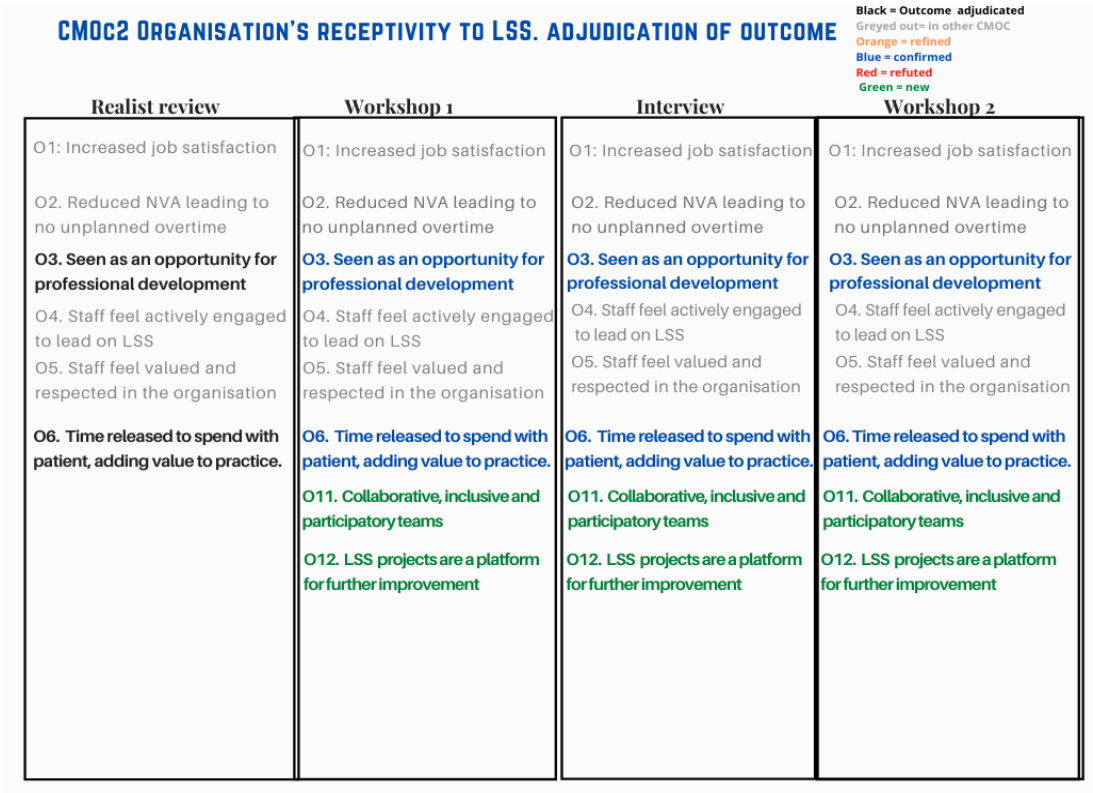
In addition, one new mechanism was identified:

- 'Provision of protected time to participate in wider Lean Six Sigma work' (M10)

There now follows the findings of participants' adjudication of outcomes for CMOc2, 'the organisation's receptivity to Lean Six Sigma'.

6.2.3 Adjudication of Outcomes for CMOc2, 'The Organisation's Receptivity to Lean Six Sigma'.

Figure 6.4 CMOc2: The Organisation's Receptivity to Lean Six Sigma - Adjudicated Outcomes



As shown in figure 6.4, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants confirmed two outcomes (O3 and O6) and generated two new outcomes (O11 and O12) for the embedded CMOc, 'the organisation's receptivity to Lean Six Sigma', (CMOc2). The confirmed outcomes are discussed first, followed by the two new outcomes. There is then discussion of participants' Lean Six Sigma project results that provide supporting evidence for the outcomes.

6.2.3.1 Adjudication of Outcome for CMOc2 - Confirmation

As shown in figure 6.4, participants adjudicated the six outcomes from the realist review and identified two as particularly relevant to CMOc2, 'the organisation's receptivity to Lean Six Sigma':

- Seen as an opportunity for professional development (O3)
- Time released to spend with patient, adding value to practice (O6)

These outcomes are now discussed.

O3: Seen as an opportunity for professional development

The opportunities for professional development were discussed in the first workshop series. Participants spoke of the opportunities to adopt new roles:

> [I] had the opportunity to take up a new [service improvement] post following my Black Belt…maternity cover but gave me great experience.
>
> P10, Practice Development Nurse, Workshop 1.

> they [Green and Black Belt] put me in a position to apply for my current and previous job.
>
> P8, Administration Team Manager, Workshop 1.

> moved from physio[therapy] to the Discharge Coordinator role…had to have process improvement qualification for this as it involves complicated frail elderly pathways.
>
> P6, Discharge Coordinator, Workshop 1.

Opportunities for further education were also discussed:

> it [Green Belt] gave me a foot on the ladder to my degree and I have continued to study since then.
>
> P13, Project Manager, Workshop 1.

> it's [Green Belt] a great opportunity to go on and develop yourself academically…something you can use in your day to day job.
>
> P20, Operations Manager, Workshop 1.

Participants spoke of the opportunity to publish their Lean Six Sigma work in peer reviewed journals:

> getting published as a result of the [Lean Six Sigma] project has been personally rewarding for me and great for my career as it's a well-cited paper.
>
> P15, Pharmacist, Interview.

> We [the Lean Six Sigma project team] published our paper on cardiac implantable devices in a quality journal…an opportunity I was glad to take up.
>
> P14, Radiology Manager, Interview.

Participants also spoke of developing new skills:

> [Lean Six Sigma] gives you a new skill set to apply to problem solving in your department.
>
> P6, Discharge Coordinator, Interview.

> you get the first-hand opportunity to apply your new skills into practice and see the impact of implementing them on a process.
>
> P19, Assistant Director of Nursing, Interview.

The opportunity to lead a team based intervention was also seen as important for professional development:

> leading a multidisciplinary team was something I had not experienced before my Green Belt…good opportunity to develop my leadership skills.
>
> P12, Physiotherapist, Workshop 2.

> leading a diverse team from outside pharmacy…opportunity to network and build relationships.
>
> P15, Pharmacist, Workshop 2.

Throughout all stages of adjudication, participants therefore confirmed their experiences of the contextual factor, 'seen as an opportunity for professional development'. They felt that this formulation adequately represented their views and experiences, and no further refinement was required.

O6: Time released to spend with patient, adding value to practice

Participants expressed the view that this outcome was an important factor in their organisation's receptivity to Lean Six Sigma work, the perception that Lean Six Sigma provided a way of releasing staff time to spend with patients:

> freeing up of physio[therapy] time to spend more contact time with my patients impacts on patient outcomes and on my job satisfaction.
>
> P12, Physiotherapist, Workshop 1.

> outcomes for patients as a result of it [Lean Six Sigma] have been phenomenal…[staff] get to spend more time with their patients, good for patient outcomes, but it also makes a more rewarding shift for them [staff].
>
> P2, Operations Manager, Workshop 1.

This participant experience was further discussed in interview:

> the staff who are in the area…are now spending more time treating their specialist patients so they're happier.
>
> P7, Service Improvement Lead, Interview.

> they[staff]see it [Lean Six Sigma education and training programme] as a way to improve processes so they can make more effective use of their time rather than being caught up in process problems.
>
> P5, Senior Medical Scientist, Interview.

And again, in the second workshop series:

> improvement in the patient wait for rehabilitation has improved by eight days…[staff] spend time working on getting the patients rehab ready, with no duplication and very little wasted time.
>
> P6, Discharge Coordinator, Workshop 2.

> we [Lean Six Sigma project team] worked on streamlining the ED (Emergency Department] triage process to free up staff and patient time…see the senior decision maker sooner and less waiting time for patients.
>
> P3, Assistant Director of Nursing, Workshop 2.

Throughout all stages of adjudication participants therefore confirmed their experiences of the contextual factor, 'time released to spend with patient, adding value to practice'. They felt that this formulation adequately represented their views and experiences, and no further refinement was required.

Summary

At the end of the adjudication process, two outcomes had been confirmed:

- 'Seen as an opportunity for professional development' (O3).
- 'Time released to spend with patient, adding value to practice' (O6).

6.2.3.2 Adjudication of Outcomes for CMOc2: New Outcomes

In the adjudication process, two new outcomes were identified for CMOc2:

- Collaborative, inclusive and participatory teams (O11)
- Lean Six Sigma projects are a platform for further improvement (O12)

Each is now discussed in turn.

O11: Collaborative, inclusive and participatory teams

Although interdisciplinary teamwork in the hospital is commonplace, participants said that they experienced working in Lean Six Sigma project teams as a new approach to team working. The ability of any staff member to access Lean Six Sigma education and training, and participate in improvement work was seen as leading to new team dynamics:

> allows really diverse staff groups to come together…gives any staff member the ability to feel supported and confident to voice within that group.
>
> P16, Speech and Language Therapist, Workshop 1.

> [the] embracing of all staff as part of a project team gives a better understanding of what team and team culture should be.
>
> P9, Clinical Nurse Specialist, Workshop 1.

Participants were familiar with the Collaborative, Inclusive and Participatory (CIP) principles as they were exposed to these in their Lean Six Sigma education and training, and these principles were used during the data collection phases of this research (chapter 4). This use of CIP principles was seen as an important factor in team formation and team working:

> respect for each other as members of a [Lean Six Sigma] team is very much there at the beginning [of Lean Six Sigma education and training], the CIP [principles], the use of the Myers Brigg [personality test], the getting to know you.
>
> P7, Service Improvement Lead, Workshop 1.

> you spend a lot of time doing the storming, norming, forming stuff with the team when you start off [Lean Six Sigma education and training]…working with CIP as you're doing it…worthwhile in the end.
>
> P13, Project Manager, Workshop 1.

Participants therefore generated a new outcome relating to this new way of team working and, being familiar with and having used CIP principles, termed it 'collaborative, inclusive and participatory teams'.

This 'way of working' within Lean Six Sigma teams was seen as feeding into practice:

> we're working together differently and with teams of people we would normally never interact with to make improvements.
>
> P5, Senior Medical Scientist, Interview.

> in a [Lean Six Sigma] team it doesn't matter where you work or who you are, every opinion is as valuable as the next.
>
> P1, Data Manager, Interview.

> the hierarchy of command is not present within the teams, it's naturally more of a co-leadership approach to change management.
>
> P 15, Pharmacist, Interview.

In the second series of workshops, this contextual factor continued to be discussed:

> [It's] more than team composition, it's an important factor, but it's also about how we work together as individuals.
>
> P16, Speech and Language Therapist, Workshop 2.

Respect for people was seen as an important component of Lean Six Sigma team working:

> [Lean] in a true sense is about respect for people and if you have a team of people who think like that then that's when we get good outcomes [from Lean Six Sigma work].
>
> P2, Operations Manager, Workshop 2.

Participants therefore generated and confirmed the new contextual factor, 'collaborative, inclusive and participatory teams'.

O12: Lean Six Sigma projects are a platform for further improvement

After completing their Lean Six Sigma education and training, all participants had engaged in further Lean Six Sigma work within their practice areas. They had experienced their project work as providing a foundation for further improvement:

> [my] Green Belt involved working with pharmacy and nursing colleagues to release time to care and my Black Belt followed on from this working with medical, nursing and pharmacy colleagues to improve drug prescription practices.
>
> P15, Pharmacist, Workshop 1.

> work I carried out on the general medicine project with the division of medicine led to my project on redesigning the frail elderly pathway…one project leads to another.
>
> P7, Service Improvement Lead, Workshop 1.

This finding of opportunities for further improvement was identified as a repeated outcome by participants.

> as you work on improvement you begin to notice even more areas for improvement which you can then work on bit by bit.
>
> P10, Practice Development Nurse, Workshop 1.

> most processes are interrelated so there you find yourself identifying more processes for improvement all the time, it's always an outcome.
>
> P1, Data Manager, Workshop 1.

This was seen as consistent with the Lean Six Sigma principle of continuous improvement and an important outcome for any Lean Six Sigma project work:

> the hip fracture pathway comprised three consecutive projects over 18 months with three different but interconnected teams so that's how each project can lead to the next…[I] was on team one but fed into teams two and three.
>
> P17, Data Coordination Lead, Interview.

> our project was on the hip fracture pathway through the [operating] theatre. We carried on from the first team and then fed into the next team for the rehab piece…parts of a whole.
>
> P18, Administration Team Manager, Interview.

The identification of further areas for improvement crossed disciplines and specialities:

> [when] I finished my work on the hip fracture project I went back to my practice area and discussed the results with them. One of the girls [in the practice area] had a great idea for a project on cancer screening and she went on to lead out on that as part of a new Lean Six Sigma team. Both of our project results are published now also, so our Lean Six Sigma work continues to encourage other people to get involved [in continuous improvement].
>
> P17, Data Coordination Lead, Workshop 2.

Participants therefore generated and confirmed a new outcome of 'Lean Six Sigma projects are a platform for further improvement'.

Summary

Two new outcomes for CMOc2 were generated in the adjudication process (figure 6.4):

- Collaborative, inclusive and participatory teams (O11)
- Lean Six Sigma projects are a platform for further improvement (O12)

The results of participants' Lean Six Sigma projects that relate to the outcomes they generated in the adjudication process are now presented.

6.2.3.3 Analysis of Lean Six Sigma Project Results that Provide Supporting Evidence for the Outcomes for CMOc2, 'The Organisation's Receptivity to Lean Six Sigma'.

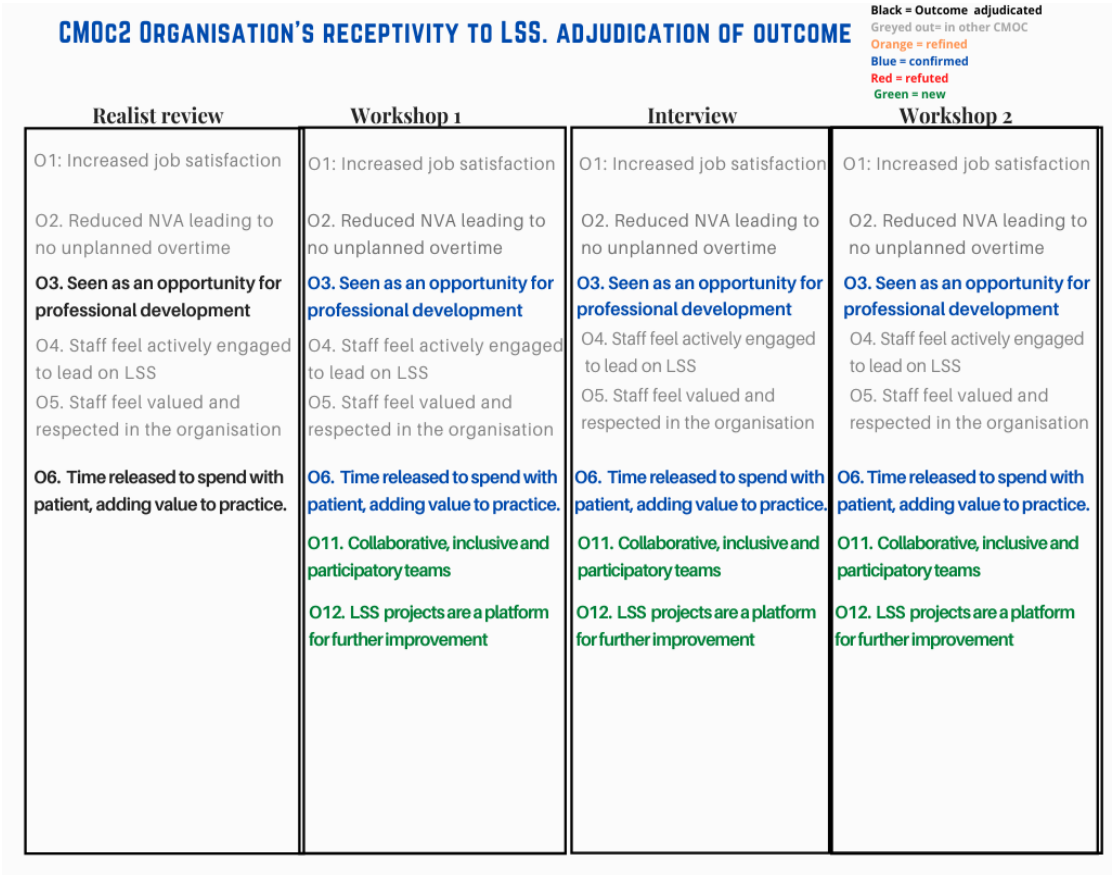
Nine participants (coded as 4,7,8,9,10,12,13,15,19) had continued their Lean Six Sigma education and training and completed the Graduate Diploma (Black Belt) with six of these (coded as 8, 9,10,12,13,15) going on to undertake an MSc in Leadership, Innovation and Management in Healthcare, congruent with Outcome O3. Ten of the participants (coded as 4, 6, 7, 8, 10, 12, 14, 15, 16 and 19) had moved to new promotional posts that had required a qualification in process improvement, again congruent with Outcome O3. Participants (coded as 7, 9, 14, 15, 16, 17 and 19) had participated in projects (Kieran et al., 2017; Creed et al., 2019; Murphy et al., 2019;

Ryan et al., 2019; Teeling et al., 2019) related to releasing time to care (Outcome O6) and as part of these had worked together in new team formations congruent with Outcome O11. A review of participant Lean Six Sigma Scientific Posters (Appendix 4.1) revealed that all participants had extensive involvement in post-qualification Lean Six Sigma improvement across the hospital congruent with Outcome O12, and they had actively encouraged and become involved in second generation projects, including cancer screening (McGrath et al., 2019) and cardiothoracic surgery (Brown et al., 2019).

The results of participants' Lean Six Sigma projects provides evidence supporting Outcomes O3, O6, O11 and O12 of the CMOc, 'the organisation's receptivity to Lean Six Sigma', (CMOc2) in their respective areas of practice. Posters summarising the projects can be found in Appendix 4.1.

6.2.3.4 Overview: Adjudication of Outcomes for CMOc2 'The Organisation's Receptivity to Lean Six Sigma'

Figure 6.4 CMOc2: The Organisation's Receptivity to Lean Six Sigma - Adjudicated Outcomes



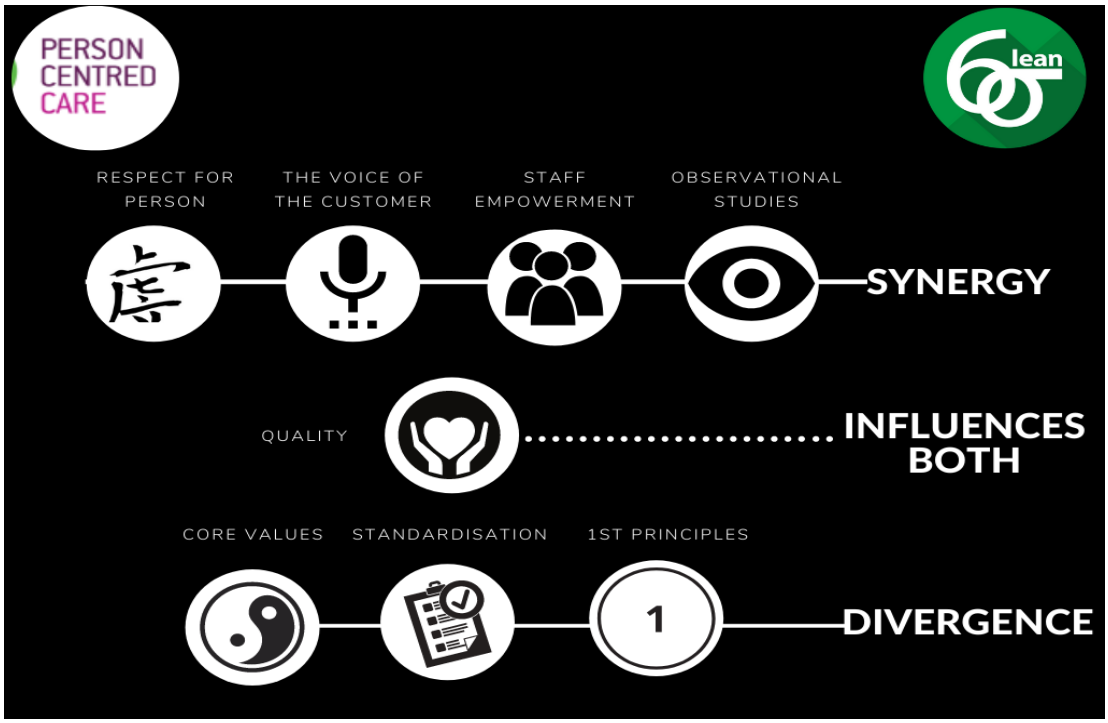
As shown again in figure 6.4, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants confirmed two outcomes (O3 and O6) and generated two new outcomes (O11 and O12) for the embedded CMOc, 'the organisation's receptivity to Lean Six Sigma', (CMOc2). The new outcomes for CMOc2 were further supported by evidence from participants' Lean Six Sigma projects (Kieran et al., 2017; Brown et al., 2019; Creed et al., 2019; McGrath et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019 and Appendix 4.1).

There now follows discussion on how CMOc2, 'the organisation's receptivity to Lean Six Sigma', aligns to the synergies and divergences of Lean Six Sigma and person-centred care and cultures.

6.2.3.5 Aligning CMOc2 to the Synergies and Divergences of Lean Six Sigma and Person-centred Care and Cultures

In chapter two, the realist review identified synergies and divergences between Lean Six Sigma and person-centred care and cultures (Figure 6.5). In the final workshop, participants discussed and clarified how, in their experiences as Lean Six Sigma practitioners, CMOc2 might align to the synergies and divergences between both methodologies.

Figure 6.5 Synergies and Divergences between Lean Six Sigma and Person-centred Care and Cultures



Source: Taken from Teeling, Dewing and Baldie (2020, p.19)

Participants identified the following:

Synergies

1. Respect for Persons. A focus on person in addition to measurement was facilitated when an overreliance on measurement and outcomes (contextual

factor C3) was absent. Contextual factor C11 (resourced practice areas) was seen as relevant to this synergy, as respectful of what resources staff need to facilitate their practice, and was also identified as relevant to Mechanisms M1 (college [training] fees paid), M7 (protected time to complete education in Lean Six Sigma) and M2 (Lean Six Sigma programme offered to all staff). Mechanism M5 (staff actively self-select and engage in programme) was felt by participants as respecting the individual's right to choose to undertake Lean Six Sigma education and training. Mechanism M10 (protected time for further work) was determined as respectful of staff time and workload. Outcomes O3 (opportunity for professional development) and O6 (time released to spend with patient) were identified as particularly relevant outcomes for an organisational culture that respects people. Outcome O11 (collaborative, inclusive and participatory teams) was seen as showing respect for the individuals' values and beliefs and respecting their considered opinions.

2. The Voice of the Customer (VOC). Where staff could feed into the development and understanding of measurements and outcomes (C3) and an overreliance on measurement was absent, the staff voice was sought and heard. Both contextual factors C10 (improvement and change are seen as achievable) and C11 (resourced practice areas) were seen as facilitating an environment conducive to staff engagement to seek out and listen to their voices. Mechanism M2 (Lean Six Sigma programme offered to all staff) was felt to be relevant to elicit the voice of staff and Mechanism M10 (protected time for further work) provided staff with the opportunity to elicit the voice of patients. Outcome O11 (collaborative, inclusive and participatory teams) was seen as congruent with seeking 'Voice of the Customer'.

3. Staff Empowerment. Staff working in practice areas where there wasn't an overreliance on measurement and outcomes (contextual factor 3) felt more empowered in their own practice. Both contextual factors C10 (improvement and change are seen as achievable) and C11 (resourced practice areas) were identified as relevant in enabling the identified Mechanisms M1 (college

[training] fees paid), M2 (Lean Six Sigma programme offered to all staff), M5 (staff actively self-select and engage in programme), M7 (protected time to complete education in Lean Six Sigma) and M10 (protected time for further work) to deliver the Outcomes O3 (opportunity for professional development), O6 (time released to spend with patient), O11 (collaborative, inclusive and participatory teams) and O12 (Lean Six Sigma projects are a platform for further improvement) that were identified by participants as empowering staff.

4. Observational Studies: Both contextual factors C10 (improvement and change are seen as achievable) and C11 (resourced practice areas) were seen as important as they provided environments conducive to observational studies or Gemba. Mechanism M10 (protected time for further work) facilitated staff participation in observational studies. Outcome O11 (collaborative, inclusive and participatory teams) was found to be particularly important for planning and reflecting on observational studies in a supportive environment.

Influencing Synergy and Divergence

1. Quality. Where staff did not perceive quality as overreliant on metrics and measurement (C3), there was potential for a more collaborative approach to measurement for improvement. Participants saw contextual factors C10 (improvement and change are seen as achievable) and C11 (resourced practice areas) as relevant enabling contexts for quality. Mechanisms M1 (college [training], fees paid), M2 (Lean Six Sigma programme offered to all staff), M5 (staff actively self-select and engage in programme), M7 (protected time to complete education in Lean Six Sigma) and M10 (protected time for further work) were identified as important in enabling staff to participate in quality and process improvement using Lean Six Sigma methodologies. All Outcomes, O3 (opportunity for professional development), O6 (time released to spend with patient), O11 (collaborative, inclusive and participatory teams) were felt to be important quality outcomes, with a particular emphasis on Outcome O12 (Lean Six Sigma projects are a platform for further improvement) to facilitate a culture of continuous improvement.

Divergence

1. Core Values. Where improvement was overreliant on measurement and perceived by staff as being all about the 'figures' (C3), participants felt that this was evidence of a divergence with person-centred cultures. However, participants identified contextual factor C11 (resourced practice areas) as one indicator that staff were valued within the organisation. Failure to respect staff's values at an individual, unit or organisational level would not, in participants' experience, facilitate good outcomes. Provision of supports such as time and funding (Mechanisms M1, M2, M7 and M10) were seen as appreciative of staff and of considering and being mindful of staff values and beliefs. Outcomes O3 (opportunity for professional development), O6 (time released to spend with patient) and O11 (collaborative, inclusive and participatory teams) were seen as outcomes when Lean Six Sigma was practiced according to its original intent for improvement through respect for persons.

2. Standardisation. Contextual factor C11 (resourced practice areas) was identified as important as it provided staff with the resources to standardise processes as required, rather than widespread and sometimes inappropriate standardisation. Mechanism M10 (protected time for further work) was seen as allowing Lean Six Sigma practitioners the time to adjudicate the processes that required standardisation in a considered way. O12 (Lean Six Sigma projects are a platform for further improvement) was determined to be an outcome that was possible through judicious and appropriate use of standardisation.

3. First Principles. Contextual factor C10 (improvement and change are seen as achievable) was considered an essential context for any Lean Six Sigma work to deliver results. All Mechanisms, M1 (college [training] fees paid), M2 (Lean Six Sigma programme offered to all staff), M5 (staff actively self-select and engage in programme), M7 (protected time to complete education in Lean Six Sigma) and M10 (protected time for further work), were seen as aligning to the

principles of person-centredness and as important mechanisms to facilitate engagement with Lean Six Sigma work. They facilitated a move from a more technical to a more person-centred approach to change. Outcome O11 (collaborative, inclusive and participatory teams) was identified as an outcome when person-centred principles are present.

6.3 Conclusion

This chapter presented the contextual factors (C), mechanisms (M) and outcomes (O) that were identified by research participants through their adjudication of CMOc2 'the organisations receptivity to Lean Six Sigma'. Lean Six Sigma practitioners' experiences at the study site indicated that improvement and change were achievable (C). They also found that the resourcing of practice areas (C) was important for process improvement to occur. The payment of college education and training fees (M) and protected time for staff (M) influenced their engagement with the Lean Six Sigma education and training programme. Further protected time (M) to carry out improvement work was identified as important for staff who were seen to actively engage in and self-select (M) for the Lean Six Sigma education and training programme. Finally, the availability of the education and training programme to all staff (M) was seen as an important for staff engagement with Lean Six Sigma. Where the identified contextual factors (C) triggered the mechanisms (M), outcomes (O) included a perception of the education and training programme as an opportunity for professional development (O) that led to time released to spend with their patients (O). Additionally, these contexts and mechanisms facilitated staff working in collaborative inclusive and participatory teams (O) that saw Lean Six Sigma projects as platforms for continuous improvement. Where there was an overreliance on measurement and outcomes (C) Lean Six Sigma practitioners indicated that it influenced their engagement with the intervention of the Lean Six Sigma education and training programme and the anticipated outcomes (O) were not achieved.

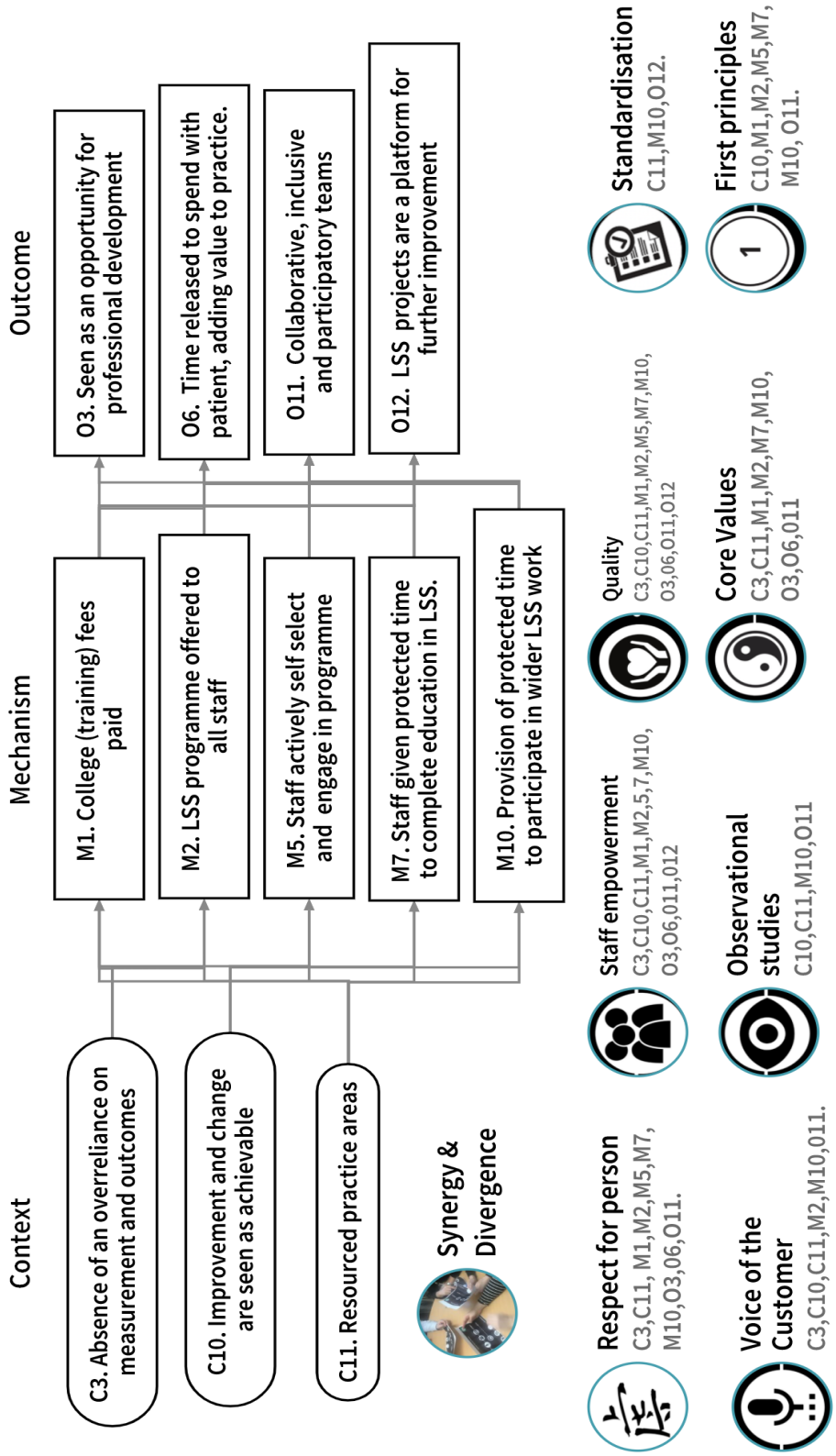
The programme theory of this research is that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures (chapter one and three) if delivered through the intervention of the UCD Lean Six Sigma education and

training programme. The visual representation of the CMOc, 'aspects of organisational culture', (figure 6.6) indicates that in relation to the intervention of the UCD Lean Six Sigma education programme, participants were able to identify:

- contextual factors (C) that facilitated or hindered their Lean Six Sigma practice work.
- the outcomes (O) that emerged because of the action of underlying mechanisms (M) which they identified as active when the contextual factors (C) were present.
- the synergies, influence and divergences between their Lean Six Sigma practice and person-centred care and cultures.

I now continue with the presentation of findings relating to the adjudication of CMOc3, 'participants' self-perception as Lean Six Sigma practitioners'

Figure 6.6 Adjudicated CMOc2 Mapped to Synergy, Influencer and Divergence

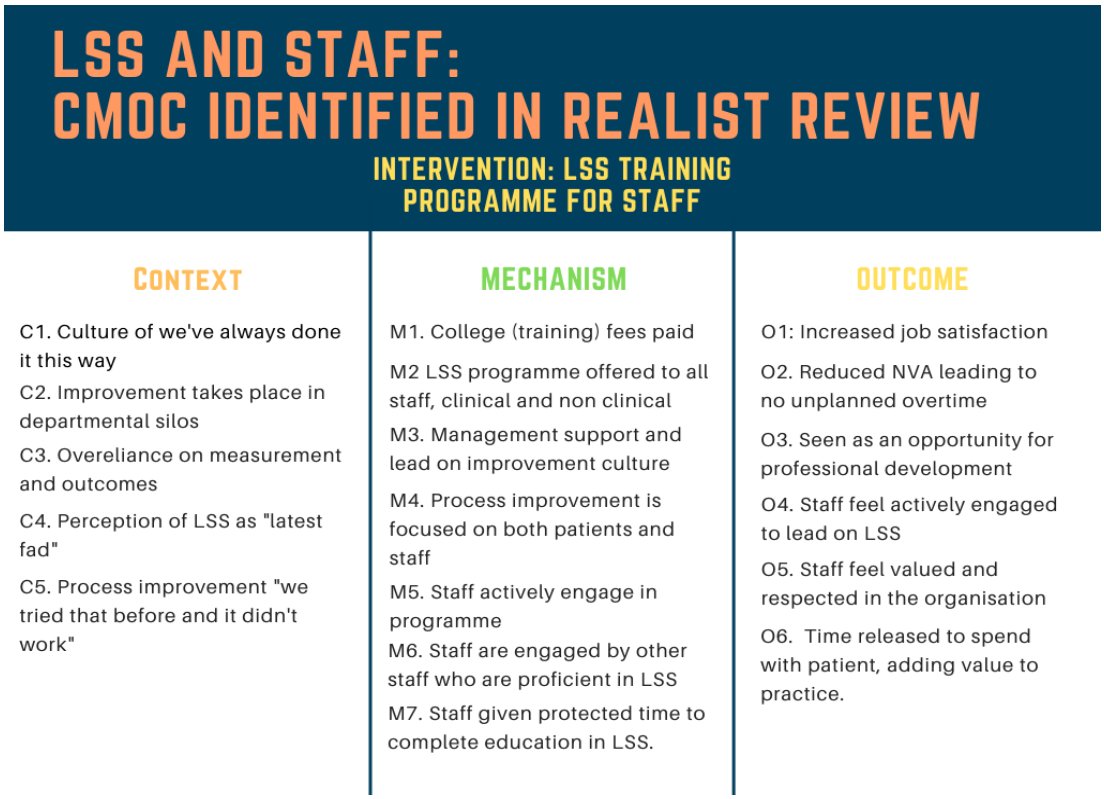


Chapter 7: CMOc3: Participants' Self-perception as Lean Six Sigma Practitioners

7.1 Introduction

This chapter again begins with reference to the CMOc, 'Lean Six Sigma and Staff', generated from the realist review (chapter 2) in which five contexts, seven mechanisms and six outcomes were identified (figure 7.1).

Figure 7.1 CMOc 'Lean Six Sigma and Staff' from the Realist Review



Participants reviewed, refined and developed this CMOc through an adjudication process comprising an initial series of workshops, twenty individual interviews and a final workshop series, as outlined in figure 4.15 (chapter 4). This refinement led to the development of three focused or embedded CMOcs, the third of which, 'participants' self-perception as Lean Six Sigma practitioners', is discussed in this chapter.

As well as confirming, refuting and refining certain of the contexts, mechanisms and outcomes shown in figure 7.1, participants identified new ones at various stages of the adjudication process (figure 4.15). Congruent with realist evaluation methodology, confirmations, refutations or refinements of the programme theory that facilitate or hinder the effectiveness of the intervention to deliver anticipated outcomes are presented, supported by illustrative quotations from participants that are representative of their collective view (Pawson & Tilley, 1997; Dobson & Fitzgerald, 2005).

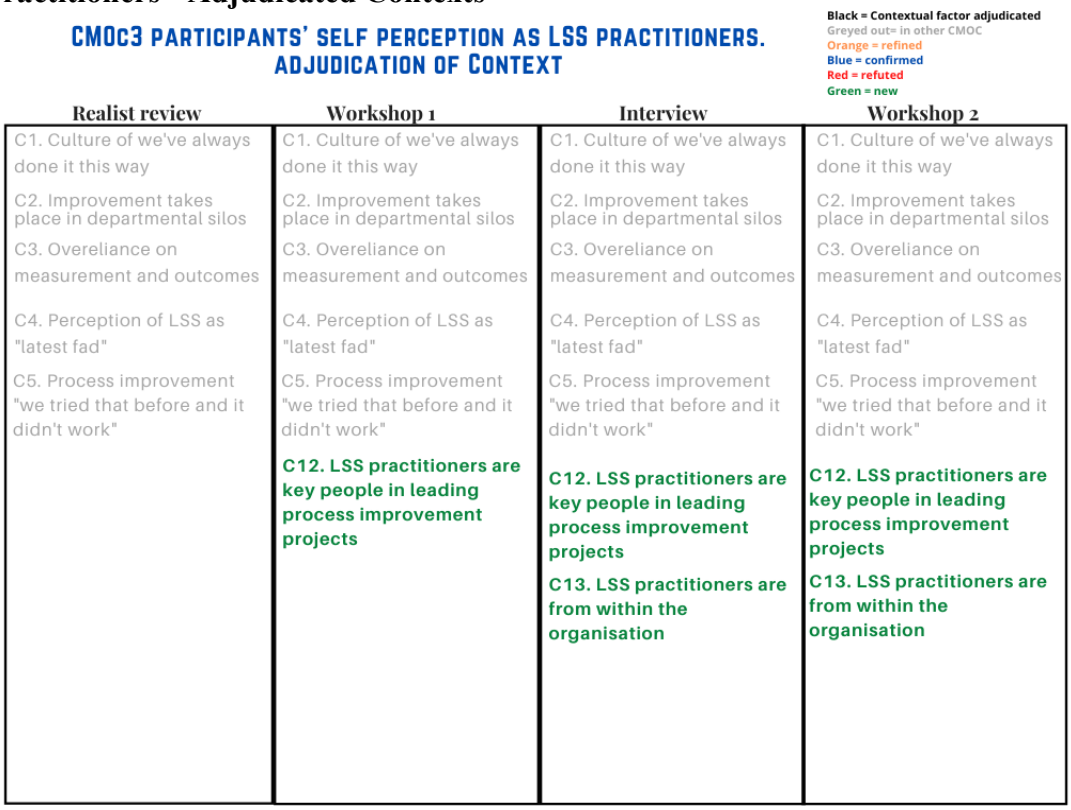
The third focused CMOc, 'participants' self-perception as Lean Six Sigma practitioners' is now discussed.

7.2 CMOc3: Participants' Self-perception as Lean Six Sigma Practitioners

This chapter begins by presenting participants' adjudication of contexts, mechanisms and outcomes for CMOc3. The chapter concludes by considering CMOc3 in terms of the synergies and divergences of Lean Six Sigma and person-centred care. The adjudication of contexts is discussed first.

7.2.1 Adjudication of Contexts for CMOc3, 'Participants' Self-perception as Lean Six Sigma Practitioners'

Figure 7.2 CMOc3: Participants' Self-Perception as Lean Six Sigma Practitioners - Adjudicated Contexts



As shown in figure 7.2, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants did not assign any contexts to the CMOc, having already located them within either CMOc1 (aspects of organisational culture, chapter 5) or CMOc2 (the organisation's receptivity to Lean Six Sigma, chapter 6). They did, however, generate two new contexts (C12 and C13) for the embedded CMOc, 'participants' self-perception as Lean Six Sigma practitioners' (CMOc3). These are now discussed.

7.2.1.1 Adjudication of Contexts for CMOc3: New Contexts

In the adjudication process, two new contextual factors for CMOc3 were identified:

- Lean Six Sigma practitioners are key people in leading process improvement projects (C12).
- Lean Six Sigma practitioners are from within the organisation (C13).

The adjudication of these is now discussed.

C12: Lean Six Sigma practitioners are key people in leading process improvement projects

In the first series of workshops, participants identified a new contextual factor based on their experience as Lean Six Sigma practitioners. They felt that they typically took the lead on process improvement projects:

> when [Lean Six Sigma improvement work] takes place, the teams are usually well populated with Green and Black Belts who spearhead the initiative and support staff involved in the change [initiative].
>
> P16, Speech and Language Therapist, Workshop 1.

> projects I've worked on that run across units involve the various process owners[staff]…generally shepherded by a Black Belt who will work with them to make the improvement.
>
> P15, Pharmacist, Workshop 1.

> the diagnostic project I worked on [as a Black Belt] had representation from every diagnostic department including Pathology, Radiology, Cardiology, Breast Health…worked alongside and supervised the team in improving [diagnostic] scheduling.
>
> P10, Practice Development Nurse, Workshop 1.

Participants noted that their leadership used both collaborative and co-leadership approaches:

> [I] spent a significant amount of my [Lean Six Sigma education and] training on how to engage, collaborate and consult with project stakeholders …has influenced my approach to process improvement.
>
> P7, Service Improvement Lead, Workshop 1.

> part of my [Lean Six Sigma education and training] included leading on teams collectively…[that's]how I work in my practice area and on bigger projects of longer duration.
>
> P8, Administration Team Manager, Workshop 1.

> [I] was part of a person-centred group within the hospital and we used CIP and PIP [purpose intention (process) and outcome and process] principles …very much influences my leadership style.
>
> P13, Project Manager, Workshop 1.

This approach to leadership and working with staff on improvement and change was further discussed in the interviews, where it was seen as well received by staff and colleagues:

> staff within [the directorate] …very amenable to working with me as the process improvement lead…held four improvement events and carried out project work with multiple teams…well supported and received.
>
> P20, Operations Manager, Interview.

> [in] physio[therapy] the therapists are very well disposed to involving in Lean Six Sigma work with one of us [a Lean Six Sigma practitioner] taking the lead…majority of staff have a White Belt…a large volume of Green [Belts]…there's a continued interest in continuous improvement.
>
> P12, Physiotherapy, Interview.

Participants experienced colleagues and staff as recognising them as leaders of improvement and change. They felt that other staff expected them to lead Lean Six Sigma project work:

> the solutions are generated from ideas that the staff [in the practice area] have for improvements, but they expect you to give direction…which is what I do.
>
> P10, Practice Development Nurse, Interview.

> [Lean Six Sigma practitioners] are routinely expected to lead on change, it's how they[staff] perceive us.
>
> P11, Discharge Coordinator, Interview.

> people [staff] come to me to help them get started with their improvement projects because they know I'm a Black Belt…see me as somebody who can give them a steer.
>
> P4, Clinical Trials Manager, Interview.

> They [staff] come to us for advice…to give some direction to their projects. We're an available resource…similar to a CNS [Clinical Nurse Specialist] leading and directing wound care, we can advise on improvement projects.
>
> P13, Assistant Director of Nursing, Interview.

Participants also self-identified as leaders on process improvement:

> [I] see myself as a leader on process improvement within the department [practice area] …chair the [Lean Six Sigma] practice group and have been the lead on projects across pathology.
>
> P5, Senior Medical Scientist, Workshop 2.

> [I] see my role as leading on process and service improvement, it's in my title, and it's what I enjoy doing.
>
> P7, Service Improvement Lead, Workshop 2.

> my current post requires me to lead on continuously improving it [frail elderly care pathway] and making sure the quality of the service is maintained.
>
> P6, Discharge Coordinator, Workshop 2.

At all stages of the adjudication of context, participants discussed the expectations of their colleagues and their own perception and recognition of themselves as key leaders of process improvement. In the second series of workshops, this was finally confirmed as a new contextual factor (C12): 'Lean Six Sigma practitioners are key people in leading process improvement projects'.

C13: Lean Six Sigma practitioners are from within the organisation

In the interviews, participants highlighted the importance of process improvement being led by Lean Six Sigma practitioners from within the organisation. Some participants had experienced Lean Six Sigma work led by external consultants prior to

the inception of the UCD education and training programme. Lack of familiarity with healthcare processes was an issue:

> terribly nice gentlemen came to work with us on an improvement project…well-meaning but had no background in healthcare and incredibly prescriptive.
>
> P16, Speech and Language Therapist, Interview.

> [the] people who we were working with knew Lean and knew all about analysers…they couldn't connect the dots back to the patient.
>
> P8, Administration Team Manager, Interview.

> [I] spent an unreasonable amount of time explaining how what they were trying to do wouldn't work without involving the community services…no understanding of healthcare processes.
>
> P19, Assistant Director of Nursing, Interview.

The scheduling of improvement events by external consultants led to frustrations for staff:

> They [outside consultants] organised an entire week to work on an intervention and we were just told to clear our calendars and attend…had to arrange cover for my patients, reschedule people and reorganise my diary…very frustrating.
>
> P6, Discharge Coordinator, Interview.

> [the] expectation to just drop everything to participate in improvement events was very unrealistic and very unfair on staff who had to stand in for us.
>
> P3, Assistant Director of Nursing, Interview.

These findings from the interviews were discussed in the second workshop series. Participants further elaborated on their experiences of external consultants. The issue of scheduling arose again:

> booking in RIE [Rapid Improvement Events] without first checking what else we have going on…timing seems to be set to suit deadlines and outputs rather than what works for staff in the speciality.
>
> P18, Administration Team Manager, Workshop 2.

> completely unrealistic expectations on staff to take part in RIE when the hospital is in escalation [high volume of patients on trolleys] …we were all very annoyed.
>
> P10, Practice Development Nurse, Workshop 2.

Participants had also experienced being offered didactic solutions by external process improvement consultants.

> we [staff] were basically told you need to do this, you need to do that…no real VOC [voice of the customer] was sought, and where it was, it was only taken on board if it was a fit with the solution they [the external consultants] offered.
>
> P15, Pharmacist, Workshop 2.

> [I] was told by them [external consultants] that I needed to get up on the ward and 'agitate' staff to get them moving…the exact word that was used. I was horrified.
>
> P6, Discharge Coordinator, Workshop 2.

Participants were unanimous in their opinion that Lean Six Sigma practitioners should be staff from within the organisation, who understood the values and culture and the ways of working. They were consistent in their thoughts that internal staff trained in Lean Six Sigma were more likely to be mindful of staff workloads, situations and feelings. They therefore generated a new contextual factor (C13) 'Lean Six Sigma practitioners are from within the organisation'.

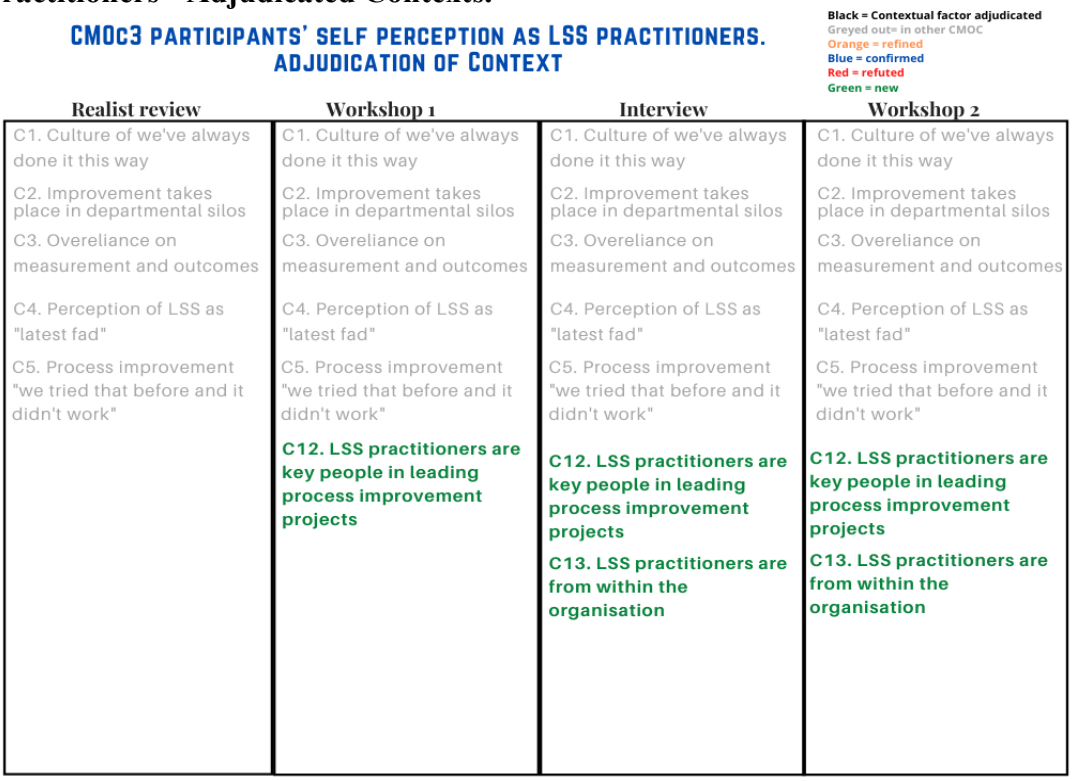
Summary

At the end of the adjudication process, two new contextual factors influencing how people engage with Lean Six Sigma were proposed:

- Lean Six Sigma practitioners are key people in leading process improvement projects (C12).
- Lean Six Sigma practitioners are from within the organisation (C13).

7.2.1.2 Overview: Adjudication of Contexts for CMOc3, 'Participants' Self-perception as Lean Six Sigma Practitioners'.

Figure 7.2 CMOc3: Participants' Self-perception as Lean Six Sigma Practitioners - Adjudicated Contexts.



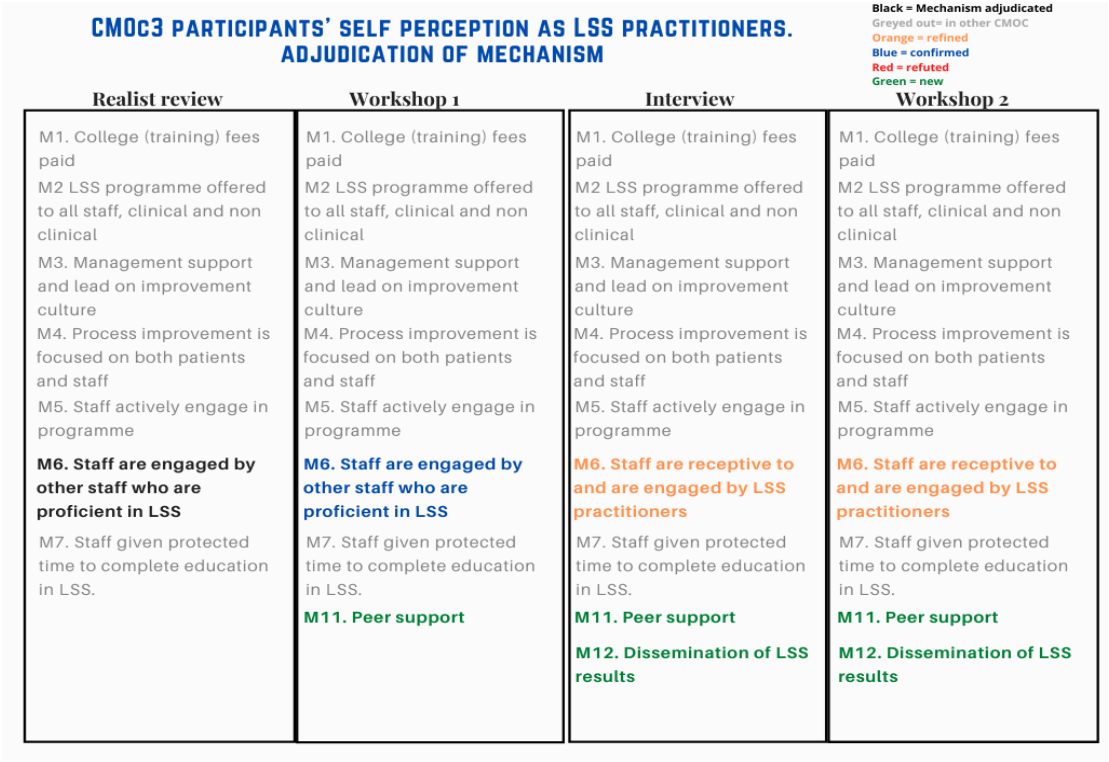
As shown again in figure 7.2, by the end of the adjudication process two new contextual factors were identified:

- Lean Six Sigma practitioners are key people in leading process improvement projects (C12).
- Lean Six Sigma practitioner are from within the organisation (C13).

The findings of participants' adjudication of mechanisms for CMOc3, 'participants' self-perception as Lean Six Sigma practitioners' are now presented.

7.2.2 Adjudication of Mechanisms for CMOc3, 'Participants' Self-perception as Lean Six Sigma Practitioners'

Figure 7.3 CMOc3: Participants' Self-perception as Lean Six Sigma Practitioners - Adjudicated Mechanisms



As shown in figure 7.3, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff' identified in the realist review, participants refined one mechanism (M6) and generated a further two (M11 and M12) for the embedded CMOc, 'participants' self-perception as Lean Six Sigma practitioners', (CMOc3). The refined mechanism is discussed first, followed by the two new mechanisms.

7.2.2.1 Adjudication of Mechanisms for CMOc3: Confirmation and Refinement

Participants adjudicated the seven mechanisms from the realist review (figure 7.3) and identified one as resonating particularly with CMOc3, 'participants' self-perception as Lean Six Sigma practitioners':

- Staff are engaged by other staff who are proficient in Lean Six Sigma (M6)

The adjudication of this mechanism is now discussed.

M6: Staff are engaged by other staff who are proficient in Lean Six Sigma

Participants discussed how they valued the presence of other Lean Six Sigma practitioners with whom they could collaborate on improvement projects:

> when I go to work on an improvement, and I see there are Belts [Lean Six Sigma practitioners] working in the area…[I] know that there is somebody really proficient and really knowledgeable and really dedicated there who is going to be really helpful.
>
> P15, Pharmacist, Workshop 1.

> being able to pull on other people is really important; I'm a Green Belt…I pull very heavily on our Black Belts for support in projects and having that access is hugely helpful…it's important that there's a person that I can approach and chat stuff through with.
>
> P16, Speech and Language Therapist, Workshop 1.

The presence of Lean Six Sigma practitioners was also seen as encouraging other staff to undertake Lean Six Sigma education and training:

> before I trained [in Lean Six Sigma] I sought out advice for a change in our department from Green Belts in my area…not only helped me but encouraged me to undertake my own [Lean Six Sigma education and] training.
>
> P11, Discharge Coordinator, Workshop 1.

> an offline discussion with one of our Black Belts was an opportunity to discuss what my expectations were from it [Lean Six Sigma education and training].
>
> P20, Operations Manager, Workshop 1.

Practitioners of Lean Six Sigma actively collaborated with and engaged staff in practice areas as part of their improvement work:

> [for] my last project we held three workshops at various stages of the VOC [voice of the customer] process to see how staff felt about the proposed change to the service…used a combination of Lean Six Sigma, Appreciative Inquiry and Person-centred approaches [in the workshops].

P12, Physiotherapy, Workshop 1.

> [I] attended the care of the elderly team case conference every week and functioned as part of the team and was 'on the agenda'…working as part of the team as opposed to outside of it.

P7, Service Improvement Lead, Workshop 1.

> [we] didn't just work with our own frail elderly team, we worked with three rehab [rehabilitation] sites over the period of eighteen months…visiting them, they visited us, and we had working groups on all strands including patient voice.

P6, Discharge Coordinator, Workshop 1.

Participants therefore confirmed the contextual factor 'staff are engaged by other staff who are proficient in Lean Six Sigma'. They confirmed the programme theory assumption that in practice areas where this mechanism is present it facilitates their engagement with Lean Six Sigma work.

In the interviews, the engagement of staff with Lean Six Sigma practitioners and their subsequent participation in collaborative, inclusive and participative project work was reiterated as a key point. Participants felt that that other staff saw them as a resource to draw on.

> you think of yourself as a resource, you're meeting people, you're communicating and you're available to each other.

P20, Operations Manager, Interview.

> [the] ability we have as Black Belts to spend time with and get peoples narrative on a situation and what they might need help with…valuable to both us and them in process improvement.

P7, Service Improvement Lead, Interview.

Another factor identified in the interviews related to colleagues' receptivity to Lean Six Sigma practitioners in the first instance. The involvement of staff by Lean Six Sigma practitioners in both identifying and agreeing the need for improvement and change within specified local processes was seen as one reason for their receptivity to Lean Six Sigma practitioners:

> [project] charters are completed in consultation with the staff in the unit so that they can give their opinion of, feed into, and are aware of what the improvement is.
>
> P18, Administration Team Manager, Interview.

In the second series of workshops, this receptivity was identified as a condition that enabled Lean Six Sigma practitioners to carry out Lean Six Sigma improvement work in practice areas:

> totally…without the staff buy in to it [Lean Six Sigma improvement work], it would be impossible to carry it [Lean Six Sigma improvement work] off.
>
> P9, Clinical Nurse Specialist, Workshop 2.

> [the] receptivity by staff within the department for Lean Six Sigma makes it far easier to try and implement change…a huge factor.
>
> P5, Senior Medical Scientist, Workshop 2.

Participants felt that the receptivity by staff to Lean Six Sigma practitioners should be captured in the confirmed CMOc, 'staff are engaged by other staff who are proficient in Lean Six Sigma' and they therefore refined it to 'staff are receptive to and are engaged by Lean Six Sigma practitioners'.

Summary

At the end of the adjudication process (figure 7.3), one mechanism had been refined from:

- Staff are engaged by other staff who are proficient in Lean Six Sigma (M6)

to:

- Staff are receptive to and are engaged by Lean Six Sigma practitioners (M6)

7.2.2.2 Adjudication of Mechanisms for CMOc3: New Mechanisms

In the adjudication process, two new mechanisms for CMOc3 were identified as follows:

- Peer support (M11)
- Dissemination of Lean Six Sigma results (M12)

Each is now discussed.

M11: Peer support

Participants said that they experienced peer support from both their practice area colleagues and their fellow Lean Six Sigma practitioners. Practice area colleagues had provided cover for Lean Six Sigma practitioners when they were involved in improvement work:

> they [practice area colleagues] were supportive in understanding the time I needed released to carry out Gemba…covered my work for the time it took.
>
> P9, Clinical Nurse Specialist, Workshop 1.

> [I] never got any kickback from my colleagues, and they were happy to cover me while I was involved in my Green Belt project.
>
> P1, Data Manager, Workshop 1.

> what I found most helpful in my 'Lean journey' was the support I received from other members of staff…giving me time to work on my project.
>
> P8, Administration Team Manager, Workshop 1.

Practice area colleagues had also provided valuable first-hand feedback on Lean Six Sigma work taking place within their units:

> the nursing staff were very frank with me with their feedback…never in a bad way but in a way that gave me real insight into the project situation.
>
> P10, Practice Development Nurse, Interview.

> [I] appreciated the feedback they [staff] gave me on the triage initiative…told me what I needed to hear as opposed to what I wanted to hear.
>
> P3, Assistant Director of Nursing, Interview.

Sometimes the support offered by colleagues was to listen to the Lean Six Sigma practitioner when they were experiencing challenges with their Lean Six Sigma work:

> after a particularly long day of trying to access data…she [a colleague] just listened to what I had to say to allow me to calm down and come down off my high.
>
> P8, Administration Team Manager, Interview.

> they [colleagues] listened to me when I explained the situation that I was experiencing with a particular consultant…offered me some suggestions on how to handle the situation.
>
> P17, Discharge Coordinator, Interview.

Overall, participants found peer support from their colleagues to be an important mechanism for their continued Lean Six Sigma work:

> one hundred percent you need the support from your colleagues in your Lean Six Sigma work…their help with Gemba, data collection or even just coffee…[colleagues] support is a real requirement for change.
>
> P15, Pharmacist, Workshop 2.

> knowing you have a bunch of people working with you who are going to have your back during the [Lean Six Sigma] project is really key to getting involved in it [Lean Six Sigma] in the first place.
>
> P6, Discharge Coordinator, Workshop 2.

The peer support from fellow Lean Six Sigma practitioners was likewise valued by participants:

> [the] support from my team in my Green Belt team was amazing – we really all helped each other out…[we] all had our own views, but we all respected and supported each other throughout the project.
>
> P4, Clinical Trials Manager, Workshop 2.

> [we] had all our storming, forming, norming stuff to do, but once we gelled, we were an effective little team…really great people to work with, so supportive, and the project worked because of the team.
>
> P10, Practice Development Nurse, Workshop 2.

Participant's also expressed that they had been supportive of other Lean Six Sigma practitioners as well as receiving support from them.

> [I] was the only admin person on my Green Belt team, but I was never made to feel I had nothing to contribute. Once the nature of the hip fracture pathway was explained to me, I was very involved…I got great support from the clinicians…they also got great support from me in running the data and crunching the numbers.
>
> P7, Data Coordination Lead, Workshop 2.

> [I] brought my ED experience to the team…helping the others to understand how the clinical teams worked there. I was able to support and carry out Gemba and also supported the team in working with the team at the CNE [Centre for Nurse Education].
>
> P3, Assistant Director of Nursing, Workshop 2.

Throughout all stages of adjudication, participants therefore discussed and confirmed their experiences of a new mechanism of 'peer support'. They felt that this formulation adequately represented their views and experiences, and no further refinement was required.

M12: Dissemination of Lean Six Sigma results

An additional mechanism identified by participants as facilitating their Lean Six Sigma practice was the dissemination of Lean Six Sigma project results. This included the display of scientific posters in practice areas:

> [we]…brainstormed what our ideal stroke unit and service would look like, how it would be perceived by our patients, by internal and external customers…took the outcomes from these workshops and represented them as scientific posters on the unit for all patients and staff to see.
>
> P12, Physiotherapy, Interview.

> our Green Belt project on releasing time to care has the results posted monthly within the department so everyone can see how we are doing…really incentivises staff to see the results of their hard work. We also send it out to all of our nursing colleagues.

P15, Pharmacist, Interview.

> [our] poster from the door to needle [Stroke pathway] project has been updated regularly since 2012…still displayed within the departments [neurology, hyper acute stroke unit, emergency department] involved in the process.

P19, Assistant Director of Nursing Interview.

> the scientific posters from our [Lean Six Sigma project] work are displayed within the department so everyone can see the process and the results.

P5, Senior Medical Scientist, Interview.

Presentations on Lean Six Sigma practice were made at local forums, committees and within practice areas:

> for our work on blood contamination rates we presented to infection control, nursing executive, nursing forum, HCA [Health Care Assistant] forum, NCHD [Non-Consultant Hospital Doctors] induction…pathology and locally to wards and units.

P10, Practice Development Nurse, Interview.

> we [the project team] held local education sessions on every ward and unit involved in the project [patient nutrition] and with the catering department and pantry staff…equated to over 30 presentations to spread the word.

P15, Speech and Language Therapist, Interview.

> large proportion of it [Black Belt] was spent presenting and discussing my findings with the medical secretaries across the directorates.

P4, Clinical Trials Manager, Interview.

Another form of dissemination identified in the second series of workshops came from the published findings of Lean Six Sigma practitioners' projects:

> it was fantastic to publish our project work, but also great to be able to direct people to a paper that they can read when they want to know more.

P15, Speech and Language Therapist, Workshop 2.

> [the work] we did with pharmacy and nursing on releasing time to care…really useful to send to our colleagues to help them understand the impact of the results.

P7, Service Improvement Lead, Workshop 2.

The posters, presentations and papers had also had national and international exposure:

> it [scientific poster] was presented at the cardiothoracic surgery annual meeting which was great.

P14, Radiology Manager, Workshop 2.

> we won the prize for best scientific poster at the Lean Symposium…presented with the trophy by the Minister for Health.

P9, Clinical Nurse Specialist, Workshop 2.

> presented our poster at the international quality conference in Amsterdam…published our findings in the International Journal for Quality in Healthcare.

P17, Data Coordination Lead, Workshop 2.

This visibility of Lean Six Sigma practitioner work through the dissemination of posters, presentations and papers was therefore identified by participants as a mechanism that encouraged staff to engage with them and become involved in Lean Six Sigma practice. Participants therefore generated a new Mechanism (M11) 'dissemination of Lean Six Sigma results'.

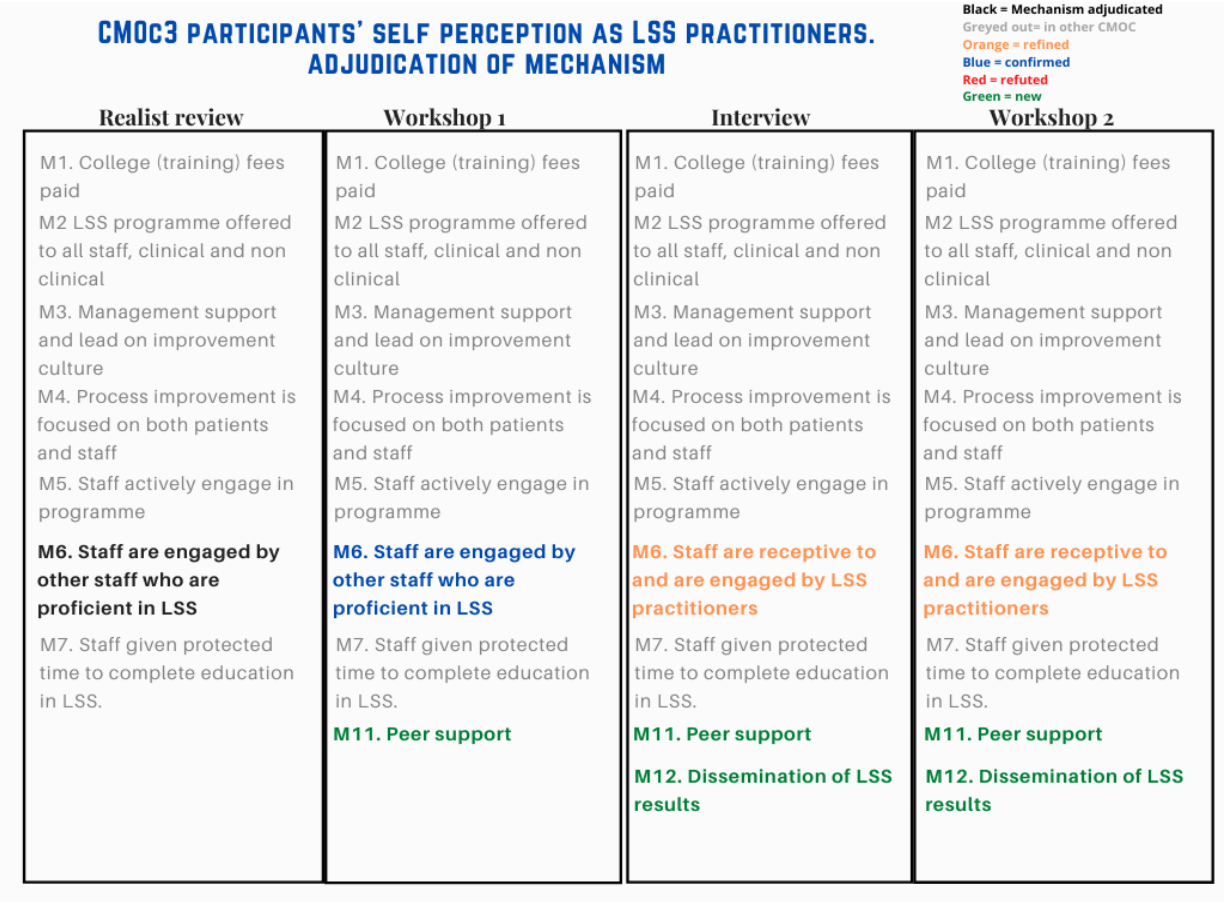
Summary

Two new mechanisms were identified in the adjudication process (figure 7.3):

- Peer support (M11)
- Dissemination of Lean Six Sigma results (M12)

7.2.2.3 Overview: Adjudication of Mechanisms for CMOc3, 'Participants' Self-perception as Lean Six Sigma Practitioners'

Figure 7.3 CMOc2: Participants' Self-perception as Lean Six Sigma Practitioners - Adjudicated Mechanisms



As shown again in figure 7.3, at the conclusion of the adjudication process one mechanism had been refined from:

- Staff are engaged by other staff who are proficient in Lean Six Sigma (M6)

to:

- Staff are receptive to and are engaged by Lean Six Sigma practitioners (M6)

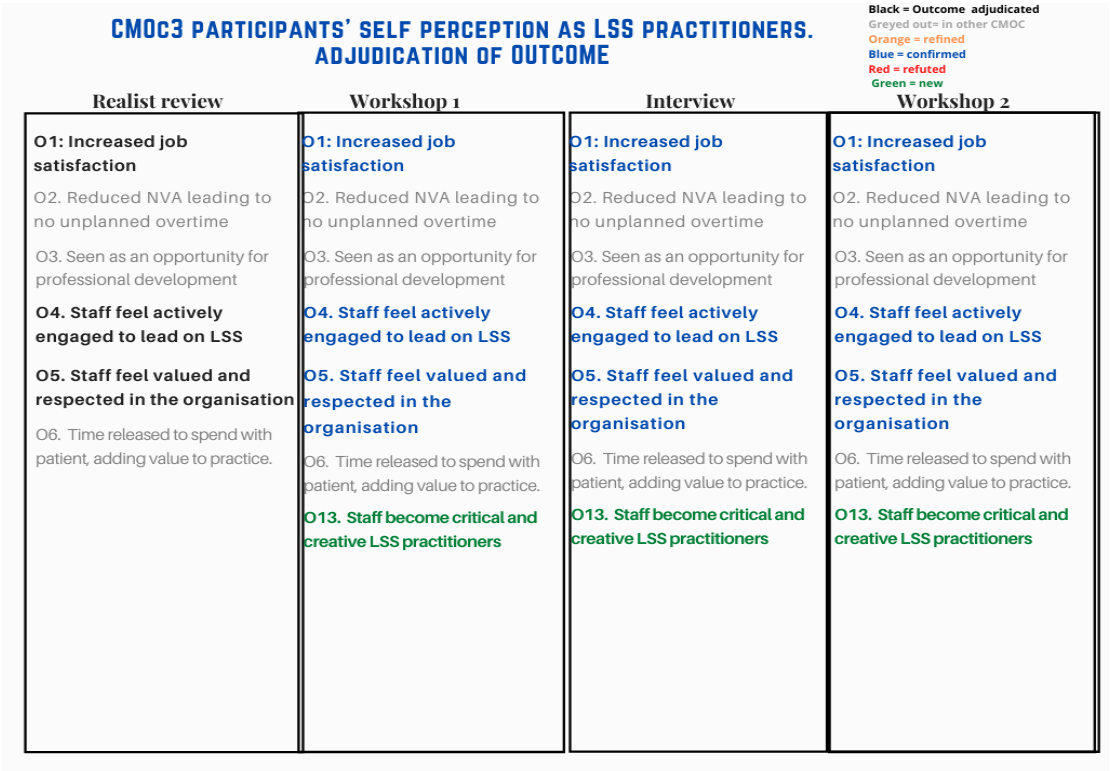
In addition, two new mechanisms were identified:

- Peer support (M11)
- Dissemination of Lean Six Sigma results (M12)

There now follows the findings of participants' adjudication of outcomes for CMOc3, 'participants' self-perception as Lean Six Sigma practitioners.'.

7.2.3 Adjudication of Outcomes for CMOc3 'Participants' Self-perception as Lean Six Sigma Practitioners'

Figure 7.4 CMOc3: Participants' Self-perception as Lean Six Sigma Practitioners - Adjudicated Outcomes



As shown in figure 7.4, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants confirmed three outcomes (O1, O4 and O5) and generated one more (O13) for the CMOc, 'participants' self-perception as Lean Six Sigma practitioners', (CMOc3). The confirmed outcomes are discussed first, followed by the three new outcomes. This is followed by a discussion of participants' Lean Six Sigma project results that provide supporting evidence for the outcomes.

7.2.3.1 Adjudication of Outcomes for CMOc3: Confirmation

As shown in figure 7.4, participants adjudicated the six outcomes from the realist review and identified three as particularly relevant to CMOc3, 'participants' self-perception as Lean Six Sigma practitioners':

- Increased job satisfaction (O1)
- Staff feel actively engaged to lead on Lean Six Sigma (O4)
- Staff feel valued and respected in the organisation (O6)

These outcomes are now discussed.

O1: Increased job satisfaction

Participants noted that they had experienced increased job satisfaction since completing their Lean Six Sigma education and training. Some participants felt this was because they had gained a new set of skills:

> working clinically in an acute public hospital…you're always so busy, but with Lean Six Sigma [education and training] you're getting new skills to help you make continuous improvements.
>
> P13, Physiotherapy, Workshop 1.

> definitely upskilling yourself…a huge element of personal reward and I'm now making improvements as part of my role and personally I get a huge amount of reward from doing that.
>
> P7, Service Improvement Lead, Workshop 1.

This experience was further confirmed in the interviews:

> [I] gained a whole new set of skills…in particular the work on stakeholder engagement and how to plan it was something I really benefitted from personally in my job.
>
> P2, Operations Manager, Interview.

> a real stretch for me to undertake the Green Belt…worth it for the skills I gained.

P17, Data Coordination Lead, Interview.

Participants felt that the Lean Six Sigma practitioners working in the organisation contributed to a more positive working environment:

> with all the Lean Six Sigma work going on…definitely people are acting differently…more considered in their attitude towards making even small changes. It makes it a far more positive working environment.
>
> P12, Physiotherapy, Interview.

> [I'm] a lot happier in my role since I completed the Green Belt…we're as busy as ever but there's a 'can do' attitude among the staff as they come back from their White, Green and now Black Belts.
>
> P5, Senior Medical Scientist, Interview.

In the second series of workshops, participants again confirmed their experience of increased job satisfaction:

> it's [Lean Six Sigma education and training] given me personal and professional satisfaction…[I'm] working with people I would never have worked with before on meaningful improvement.
>
> P13, Project Manager, Workshop 2.

> huge job satisfaction…personal and professional development…really changed my career pathway in a good way.
>
> P8, Administration Team Manager, Workshop 2.

Contributing to or involving in Lean Six Sigma project work was identified as contributing to increased job satisfaction:

> felt proud of the contribution we made to improving patient experiences in the ED [Emergency Department] …certainly increased my job satisfaction.
>
> P3, Assistant Director of Nursing, Workshop 2.

> as the results [of Lean Six Sigma project work] became apparent, I really experienced increased job satisfaction…my contribution was recognised…suggestions were implemented.

P20, Operations Manager, Workshop 2.

Throughout all stages of adjudication participants therefore discussed and confirmed their experiences of the outcome of 'increased job satisfaction'. They felt that this formulation adequately represented their views and experiences, and no further refinement was required.

O4: Staff feel actively engaged to lead on Lean Six Sigma

In the first series of workshops, participants expressed that they felt both capable and engaged to lead on Lean Six Sigma improvements within the organisation.

> my husband and me are cavers and we use chisels…with Lean I'm the little chisel. I'm chiselling away at a boulder that blocks improvement, but I feel I can do it since I became a Green Belt.
>
> P5, Senior Medical Scientist, Workshop 1.

> [I] feel confident and capable to go and participate in project work in other departments…quite comfortable in using and leading it [Lean Six Sigma].
>
> P13, Project Manager, Workshop 1.

> through Lean I have a better understanding of the hospital processes that have given me that confidence in my improvement work and leading on next generation projects.
>
> P6, Discharge Coordinator, Workshop 1.

Participants felt that as Lean Six Sigma practitioners they could actively lead on improvement and change projects:

> we spent 3 years trying to change the way that we were processing scopes [nasopharyngoscopy scopes] but it involved changing from the traditional convoluted process. When we used a Lean approach, I was much more engaged to lead on the change, and people came on board. We had the change in place in 5 weeks.
>
> P16, Speech and Language Therapist, Interview.

> [I] never really had the confidence to engage stakeholders by myself, but it [Lean Six Sigma education and training programme] has given

> me the skills to engage people and shown me how to lead on change initiatives with confidence…it's really helped.
>
> P7, Service Improvement Lead, Interview.

Participants expressed that they were actively engaged by their managers and colleagues to participate in or lead on Lean Six Sigma projects:

> whenever there is an RIE [Rapid Improvement Event] the call goes out to all the Belts [Lean Six Sigma practitioners within the hospital] and we start to pull project teams together.
>
> P7, Service Improvement Lead, Workshop 2.

> we actively look for help from external [to the department] Lean people [practitioners] to assist on our lab-based work…fresh eyes for Gemba…breaks any silo mentality.
>
> P5, Senior Medical Scientist, Workshop 2.

> [I've] participated in so many projects at this stage…they come looking for me as I've worked on similar projects or have something of value to add to the discussion.
>
> P13, Project Manager, Workshop 2.

Throughout all stages of adjudication participants therefore discussed and confirmed their experiences of the outcome, 'staff feel actively engaged to lead on Lean Six Sigma'. They felt that this formulation adequately represented their views and experiences, and no further refinement was required.

O5: Staff feel valued and respected in the organisation

Participants spoke of how, as Lean Six Sigma practitioners, they engaged with other staff and colleagues in ways that might enable them to feel valued:

> actively trying to engage other staff in the process improvement…I involve them in any and all decision making, hopefully making them feel valued and empowered.
>
> P14, Radiology Manager, Workshop 1.

> [I] try to be collaborative in the continuous improvement process, we [practice area colleagues] have really worked hard to make sure staff feel included and that their voice is heard.

P5, Senior Medical Scientist, Interview.

> we [Lean Six Sigma practitioners] frame our improvement workshops with the CIP and PIP principles…the intention is to make everyone feel included from the start.

P13, Project Manager, Workshop 1.

Working with staff in a collaborative, inclusive and participatory manner was seen as resulting in staff feeling valued and respected.

> people involved in projects feel that their opinion and expertise is both heard and appreciated. They respect us respecting them.

P19, Assistant Director of Nursing, Workshop 1.

This was reaffirmed in the interviews:

> keeping people in the loop and actually taking on board what they say to you as opposed to offering lip service in response to their input, that makes them feel respected and valued, I've seen it in so many projects.

P8, Administration Team Manager, Interview.

> the fact that my input was sought was what first got me interested in doing the (Lean Six Sigma education and training) programme myself. I felt that my opinion counted.

P3, Assistant Director of Nursing, Interview.

In the second series of workshops, participants also expressed that they themselves felt valued and respected:

> there's been a lot of investment in staff through Lean Six Sigma…made me feel as if I mattered too…my opinions were valued.

P18, Administration Team Manager, Workshop 2.

> It [Lean Six Sigma education and training] was an opportunity for me to be part of something bigger and to have my contribution recognised and valued.

P17, Discharge Coordinator, Workshop 2.

> people [colleagues and staff] respect your opinion and your expertise as a Black Belt and it certainly gives you that sense of being valued by others.
>
> P4, Clinical Trials Manager, Workshop 2.

Throughout all stages of adjudication participants therefore discussed and confirmed their experiences of the outcome, 'staff feel valued and respected in the organisation'.

Summary

At the end of the adjudication process, three outcomes were confirmed:

- Increased job satisfaction (O1)
- Staff feel actively engaged to lead on Lean Six Sigma (O4)
- Staff feel valued and respected in the organisation (O6)

7.2.3.2 Adjudication of Outcomes for CMOc3: New Outcome

In the adjudication process, one new outcome was identified as part of CMOc3:

O3: Staff become critical and creative Lean Six Sigma practitioners

A new outcome generated by participants in the first workshop series related to how they thought about process improvement having completed their Lean Six Sigma education and training:

> [Lean Six Sigma education and training] influenced the way I think about problem solving…I approach things differently.
>
> P13, Project Manager, Workshop 1.

> the training has given me a new perspective on how to organise processes – even at home.
>
> P1, Data Manager, Workshop 1.

> it [Lean Six Sigma education and training] made me realise the importance of measurement and capturing an accurate picture…made me take a more critical approach to problem solving.

P4, Clinical Trials Manager, Workshop 1.

Participant's perceived themselves as critical thinkers:

> when I was tackling a problem before [Lean Six Sigma education and training] I jumped straight to solutions without looking for the root cause…far more measured in my solution building now…a more critical thinker.
>
> P15, Pharmacist, Workshop 1.

> [I] don't just go along with other peoples' conclusions anymore…[I'm] constantly asking Why…using the 5Whys [root cause analysis tool] to understand the problem.
>
> P3, Assistant Director of Nursing, Workshop 1.

> [I] am way more critical in my thinking…approach problems in a far more systematic and consistent way.
>
> P14, Radiology Manager, Interview.

Education on reflective techniques from the UCD education and training programme such as the Deming wheel (Plan, Do, Check, Act) enabled participants' critical thinking:

> [the PDCA] gives me a focus for my project work that has the pause button to stop and check…time to think…to make sure I am not racing ahead…which was always a problem for me.
>
> P6, Discharge Coordinator, Interview.

> using triads [a coaching model] in our training and since with other Belts has proven a really useful way to reflect and get honest feedback…allows you to think about the problem in a different way.
>
> P13, Project Manager, Interview.

> [a] simple thing like 'what worked/what didn't work' following my workshops really made me take on board the staff feedback…I have found myself thinking differently.
>
> P12, Physiotherapy, Interview.

Participants also noted that they were more creative in their thinking since completing their Lean Six Sigma education and training:

> [with] no budget for any of the project work I've undertaken…had to think really creatively…generating solutions that are cost effective and easy to implement.
>
> P14, Radiology Manager, Interview.

> a major factor in our success in the SDU [Surgical Day Unit] was the very creative use of coloured clothes pegs…I still tell that story at every opportunity.
>
> P8, Administration Team Manager, Interview.

> the creativity that went into the GIM [General Internal Medicine] project was unbelievable…developing new workshop formats the whole time.
>
> P7, Service Improvement Lead, Interview.

In the second series of workshops, Lean Six Sigma education and training was again identified by participants as influencing how they thought:

> [Lean Six Sigma education and training] really made me think about evaluating things before I even attempt to change them; it's made me approach going about change very differently.
>
> P18, Administration Team Manager, Workshop 2.

> very much with the Lean training you think about things differently, you think outside the box and you break the problem down into bitesize pieces.
>
> P13, Project Manager, Workshop 2.

> there's a greater understanding of the reasons for wanting to change the way things are done when you're a Green Belt.
>
> P6, Discharge Coordinator, Workshop 2.

Throughout all stages of adjudication participants therefore discussed and confirmed their experiences of the outcome, 'staff become critical and creative Lean Six Sigma practitioners'.

Summary

One new outcome for CMOc3 was generated in the adjudication process (figure 7.4):

- Staff become critical and creative Lean Six Sigma practitioners (O13)

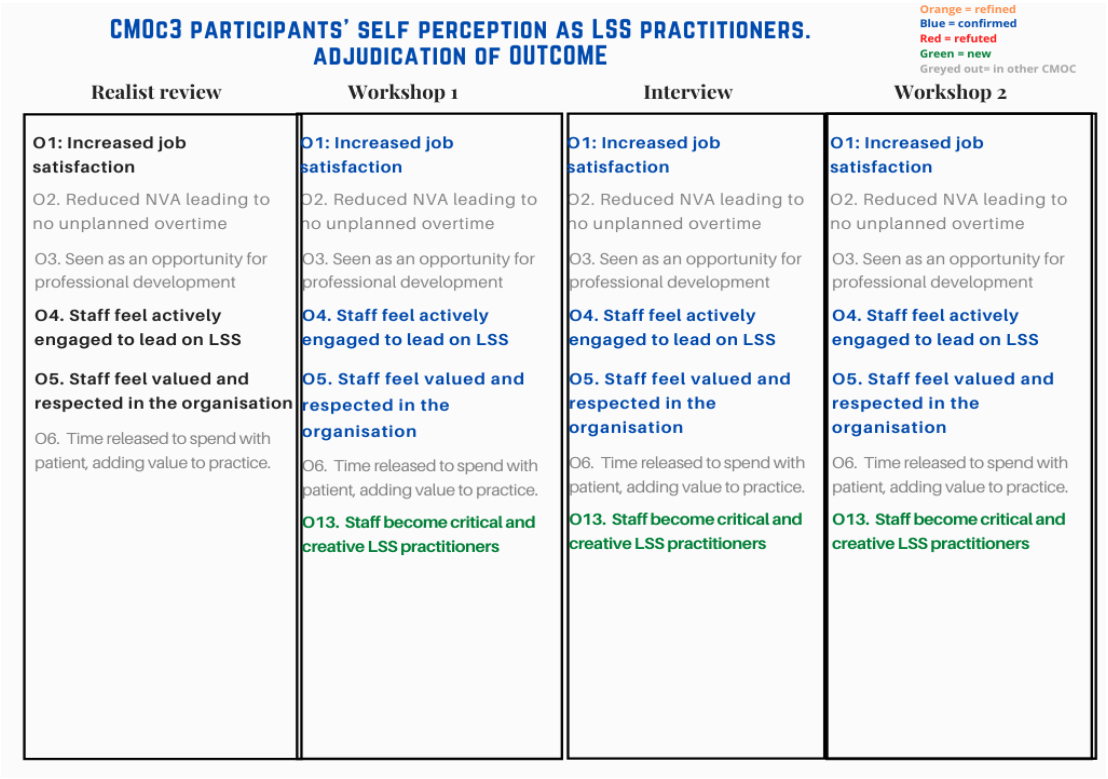
There now follows the results of participants' Lean Six Sigma projects that are relevant to the outcomes they generated in the adjudication process.

7.2.3.3 Analysis of Lean Six Sigma Project Results that Provide Supporting Evidence for the Outcomes for CMOc3, 'Participants' Self-perception as Lean Six Sigma Practitioners'.

Job satisfaction among staff (Outcome O1) was noted as improving after Lean Six Sigma improvements in practice areas (O'Hora et al., 2015; Kieran et al., 2017; Brown et al., 2019; Davies et al., 2019). All participants had actively participated in and led on process and quality improvement initiatives using Lean Six Sigma (Outcome O4) with many of the initiatives published in peer reviewed journals (Hayden et al., 2016; Kieran et al., 2017; Brown et al., 2019; Creed et al., 2019; Hynes et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019). There was evidence that staff who were involved in Lean Six Sigma interventions felt their opinions were respected (Outcome O5) (Kieran et al., 2016; Davies et al., 2019, Teeling et al., 2019). The value attached to staffs' feelings (Outcome O5) and their input into Lean Six Sigma projects was reflected in a number of projects focused on releasing time for patient care (Appendix 4.1), where staff participation was seen as invaluable. The location of the Lean Six Sigma education and training programme within existing conceptual frameworks was seen as enabling participants to become creative, critical and innovative Lean Six Sigma practitioners (McNamara & Teeling, 2019) with a focus on staff wellbeing and patient outcomes, congruent with Outcome O13. The results of participants' Lean Six Sigma projects provides evidence supporting Outcomes O1, O4, O5 and O13 of the CMOc, 'participants' self-perception as Lean Six Sigma practitioners', (CMOc3) in their respective areas of practice. Posters summarising the projects can be found in Appendix 4.1.

7.2.3.4 Overview: Adjudication of Outcomes for CMOc3 'Participants' Self-perception as Lean Six Sigma Practitioners'

Figure 7.4 CMOc3: Participants' Self-perception as Lean Six Sigma Practitioners - Adjudicated Outcomes



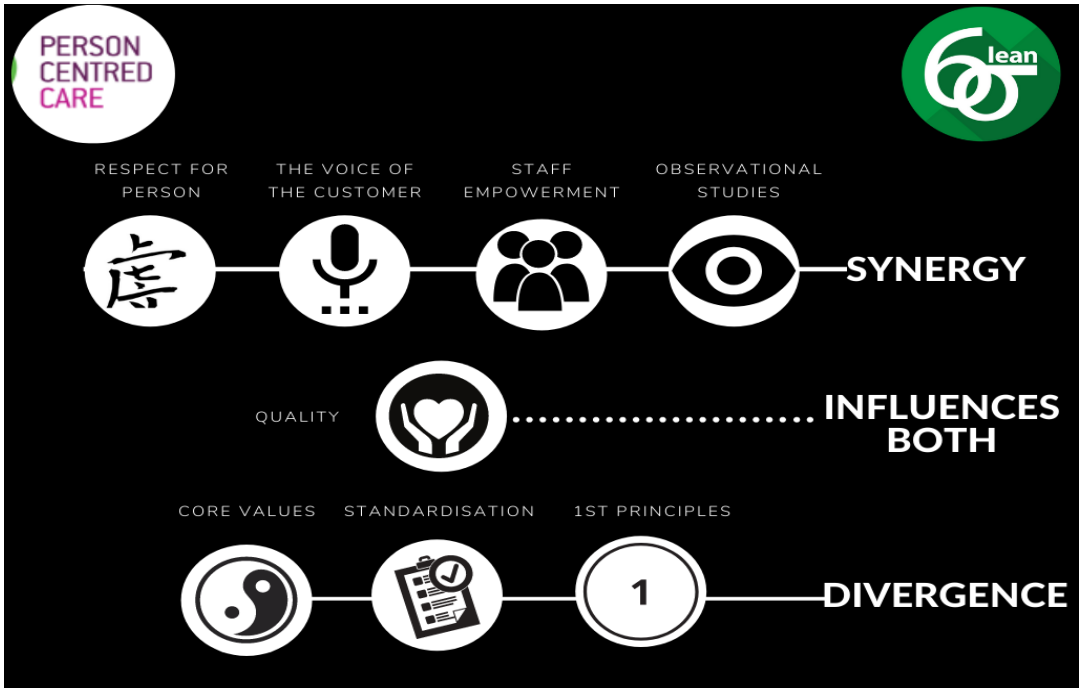
As shown again in figure 7.4, in the course of the adjudication process of the CMOc, 'Lean Six Sigma and Staff', identified in the realist review, participants confirmed three outcomes (O1, O4 and O5) and generated one more (O13) for the embedded CMOc, 'participants' self -perception as Lean Six Sigma practitioners', (CMOc3). The outcomes for CMOc3 were further supported by evidence from participants' Lean Six Sigma projects (O'Hora et al., 2015: Kieran et al., 2017; Brown et al., 2019; Creed et al., 2019; McGrath et al., 2019; Murphy et al., 2019; Ryan et al., 2019; Teeling et al., 2019 and Appendix 4.1).

There now follows discussion of how CMOc3, 'participants' self-perception as Lean Six Sigma practitioners', aligns to the synergies and divergences of Lean Six Sigma and person-centred care and cultures.

7.2.3.5 Aligning CMOc3 to the Synergies and Divergences of Lean Six Sigma and Person-centred Care and Cultures

In chapter two, the realist review identified synergies and divergences between Lean Six Sigma and person-centred care and cultures (Figure 7.5). In the final series of workshops, participants discussed and clarified how, in their experiences as Lean Six Sigma practitioners, CMOc3 might align to the synergies and divergences between both methodologies.

Figure 7.5 Synergies and Divergences between Lean Six Sigma and Person-centred Care and Cultures



Source: Taken from Teeling, Dewing and Baldie (2020, p.19)

Participants identified the following:

Synergies

1. Respect for Persons. Participants identified contextual factor C13 (Lean Six Sigma practitioners are from within the organisation) as an indicator that staff were respected in the organisation and seen as capable of leading on change themselves (contextual factor C12, Lean Six Sigma practitioners are key people

in leading process improvement). Mechanism M11 (peer support) was identified as colleagues respecting and supporting each other when involved in process improvement. Outcome O5 (staff feel valued and respected in the organisation) was seen as a key outcome synergistic with respect for persons.

2. The Voice of the Customer (VOC). Both contextual factors C12 (Lean Six Sigma practitioners key people in leading process improvement) and C13 (Lean Six Sigma practitioners are from within the organisation) were seen as important as they situated Lean Six Sigma practitioners in a place where engaging with other staff was possible. Mechanism M6 (staff are receptive to and are engaged by Lean Six Sigma practitioners) was felt to be an important mechanism to elicit the voice of staff. Outcome O5 (staff feel valued and respected in the organisation) was seen as a result of successfully seeking and engaging with the 'Voice of the Customer'.

3. Staff Empowerment. Both contextual factors C12 (Lean Six Sigma practitioners key people in leading process improvement) and C13 (Lean Six Sigma practitioners are from within the organisation) were identified as relevant in enabling Mechanism M11 (peer support) to facilitate the Outcomes O1 (increased job satisfaction), O4 (staff feel actively engaged to lead on Lean Six Sigma), O5 (staff feel valued and respected in the organisation) and O13 (staff become critical and creative Lean Six Sigma practitioners) that were identified by participants as empowering staff.

4. Observational Studies: Both contextual factors C12 (Lean Six Sigma practitioners are key people in leading process improvement) and C13 (Lean Six Sigma practitioners are from within the organisation) were seen as important because they enabled observational studies and Gemba to be undertaken by staff local to the organisation and familiar with its ways of working. Mechanism M6 (staff are receptive to and are engaged by Lean Six Sigma practitioners) was determined to be relevant as it provided an environment conducive to observational studies. Outcome O4 (staff feel

actively engaged to lead on Lean Six Sigma) was seen as related to successful observational studies, and the involvement of local practice area staff was seen as leading to Outcome O5 (staff feel valued and respected in the organisation).

Influencing Synergy and Divergence

1. Quality. Participants saw both contextual factors C12 (Lean Six Sigma practitioners key people in leading process improvement) and C13 (Lean Six Sigma practitioners are from within the organisation) as relevant enabling contexts for quality. Mechanism M6 (staff are receptive to and are engaged by Lean Six Sigma practitioners) was identified as contributing to quality-of-care outcomes. Mechanism M11 (dissemination of Lean Six Sigma results) was established as being of particular importance in communicating the impact of Lean Six Sigma on quality of care. All Outcomes, O1 (increased job satisfaction), O4 (staff feel actively engaged to lead on Lean Six Sigma), O5 (staff feel valued and respected in the organisation) and O13 (staff become critical and creative Lean Six Sigma practitioners) were seen as facilitating a culture of continuous improvement.

Divergences

1. Core Values. Participants identified contextual factor C13 (Lean Six Sigma practitioners are from within the organisation) as an indicator that staff were valued within the organisation and seen as capable of leading on change themselves (contextual factor C12, Lean Six Sigma practitioners key people in leading process improvement). Mechanism M11(peer support) was singled out as providing staff with an opportunity to discuss what they valued with supportive colleagues in a supportive environment. Outcome O5 (staff feel valued and respected in the organisation) was identified as an outcome whereby Lean Six Sigma was practiced according to its original intent for improvement through respect for persons.

2. Standardisation. Participants saw both contextual factors C12 (Lean Six Sigma practitioners key people in leading process improvement) and C13 (Lean Six Sigma practitioners are from within the organisation) as relevant to standardisation. The presence of trained Lean Six Sigma practitioners from within the organisation would facilitate an understanding of where and when to use standardised processes as opposed to widespread and sometimes inappropriate standardisation. Mechanism M6 (staff are receptive to and are engaged by Lean Six Sigma practitioners) was seen as providing Lean Six Sigma practitioners and other staff time to adjudicate the processes that required standardisation in a considered way. Outcomes O4 (staff feel actively engaged to lead on Lean Six Sigma), O5 (staff feel valued and respected in the organisation) and O13 (staff become critical and creative Lean Six Sigma practitioners) were classified as outcomes when staff were consulted by and guided by creative Lean Six Sigma practitioners in the appropriate use of standardisation in processes.

3. First principles. Contextual factors C12 (Lean Six Sigma practitioners are key people in leading process improvement) and C13 (Lean Six Sigma practitioners are from within the organisation) were identified as essential to understanding the complex social interactions in practice areas. Mechanisms M6 (staff are receptive to and are engaged by Lean Six Sigma practitioners) and M11 (peer support) facilitated a move from a more technical to a more person-centred approach to change. Outcomes O1 (increased job satisfaction), O4 (staff feel actively engaged to lead on Lean Six Sigma) and O5 (staff feel valued and respected in the organisation) were identified as outcomes when person-centred principles are present.

7.3 Conclusion

This chapter has presented the contextual factors (C), mechanisms (M) and outcomes (O) that were identified by research participants through their adjudication of CMOc3, 'participants' self-perception as Lean Six Sigma practitioners'. The study site did not

use external consultants to lead on improvement work but rather internal staff who were Lean Six Sigma practitioners (C). The organisation viewed these staff as leaders in their ongoing process improvement work (C). Lean Six Sigma practitioners engaged with staff who were receptive to them (M) and who were encouraged to engage in Lean Six Sigma improvement work by the dissemination of the results of previous work (M) relating to patient and staff experiences of care, and patient outcomes. Peer support from colleagues and other Lean Six Sigma practitioners (M) was also seen as an important factor in supporting practitioners in their work. Where the identified contextual factors (C) triggered the mechanisms (M), outcomes included staff feelings of increased job satisfaction (O), staff feeling valued and respected, and engaged to lead on improvement work (O). Finally, participants felt that they had become more creative and critical thinkers since engaging with Lean Six Sigma education and training (O). A series of diagrams illustrating the fully elaborated, incremental development of CMOc3 through all stages of participant adjudication, including its mapping to the synergies and divergences between the Lean Six Sigma and person-centred care methodologies is presented in Appendix 7.1. The final adjudicated CMOc3, reflecting the results of all stages of adjudication is shown in figure 7.6.

The programme theory of this research is that Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures (chapters one and three) if delivered through the intervention of the UCD Lean Six Sigma education and training programme. The visual representation of the CMOc, 'participants' self-perception as Lean Six Sigma practitioners' (figure 7.6) indicates that in relation to the intervention of the UCD Lean Six Sigma education programme, participants were able to identify:

- contextual factors (C) that facilitated or hindered their Lean Six Sigma practice work.
- the outcomes (O) that emerged because of the action of underlying mechanisms (M) which they identified that were active when the contextual factors (C) were present.

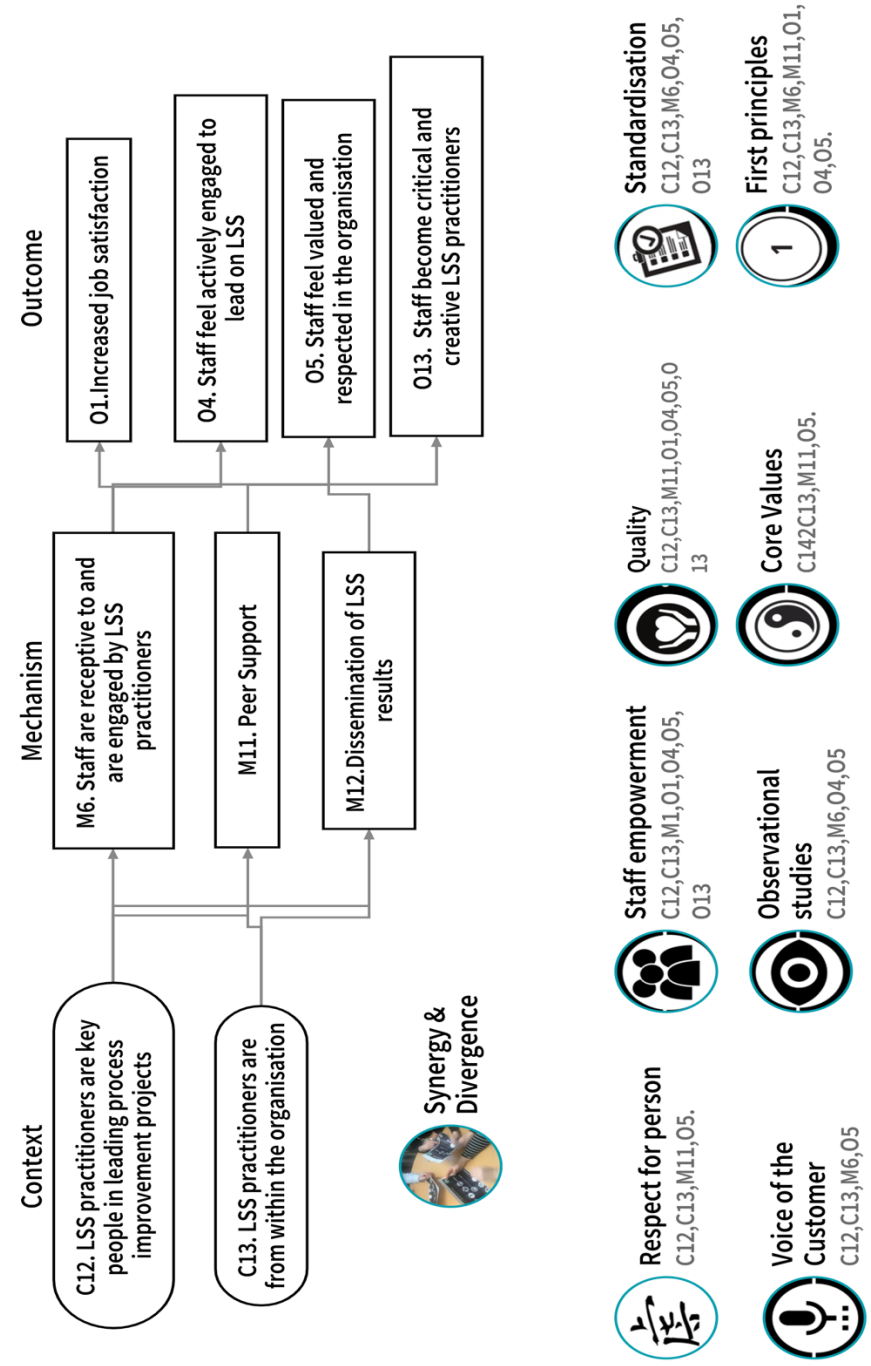
- the synergies, influencer and divergences between their Lean Six Sigma practice and person-centred care and cultures.

Finally, a summary of the findings of this study. Chapters five, six and seven have set out the experiences of people who have experienced the intervention of the UCD Lean Six Sigma education and training programme and draw upon those collective experiences to adjudicate the initial programme theory of 'Lean Six Sigma can have a positive influence on person-centredness, person-centred care and person-centred cultures if delivered through the intervention of the UCD Lean Six Sigma education and training programme'. Following development of the programme theory, a realist review of the literature was undertaken to develop three CMOcs relating to Lean Six Sigma and Patients, Lean Six Sigma Staff, and Lean Six Sigma and the Organisation (chapter two). The CMOc, Lean Six Sigma and Staff, was 'tested' through adjudication by research participants using a series of person-centred workshops, individual semi-structured realist interviews and a review of the results of their Lean Six Sigma project work. Following this adjudication, three more focused or embedded CMOcs were developed:

CMOc 1. Aspects of organisational culture (Chapter 5)
CMOc 2. The organisation's receptivity to Lean Six Sigma (Chapter 6)
CMOc 3. Participants' self-perception as Lean Six Sigma practitioners (Chapter 7)

This enabled identification of findings concerning the contextual factors (C) that were required to facilitate the outcomes (O) that emerged because of the action of underlying mechanisms (M) which were identified as active when the contextual factors (C) were present. It also enabled identification of the synergies, influencer and divergences between participants' Lean Six Sigma practice and person-centred care and cultures. The next chapter discusses the implications of the study findings for practice, education and future research as well as the challenges, limitations and delimitations of the study.

Figure 7.6 Adjudicated CMOc3 mapped to synergy, influencer and divergence



Chapter 8: Discussion

8.1 Introduction

The aim of this research was to evaluate the programme theory 'Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD Lean Six Sigma education and training programme', by asking *whether, to what extent and in what ways, Lean Six Sigma in healthcare contributes to person-centred care and cultures*. This chapter discusses how this question has been addressed. This research is original because, based on realist review (chapter two), it is the first to use realist evaluation (Pawson & Tilley 1997) to evaluate the contribution of Lean Six Sigma to person-centred care and person-centred cultures. Because the study was investigating person-centredness, person-centred values and principles guided the design and conduct of the realist evaluation. Although realist review and evaluation have been used to evaluate the delivery of person-centred care in practice settings (McCormack et al., 2006; Pearson et al., 2015; Bunn et al, 2017; Taylor et al, 2015; Dickson et al., 2017; Tennant et al., 2020), this research is also original in its combined use of person-centred and realist evaluation research methods to inform its design and implementation (chapter four).

Undertaking a realist review (chapter two) of the literature established that there is a lack of theoretical and empirical research in this area. As discussed in section 2.5.6 Lean practitioners are often unaware of, or pay little attention to Lean's philosophical roots, or fail to have an understanding of Lean as a philosophy (Imai, 1986; Wittenberg, 1994; Gondhalekar et al., 1995; Bateman, 2002; Olexa, 2002a,b; Liker, 2004; Teeling, Dewing & Baldie, 2020). The review identified that Lean Six Sigma was used less as an organisational philosophy (Lawal et al., 2014; Flynn et al., 2018) but more as a quality improvement tool for continuous improvement (Radnor et al., 2012). Recent work by Wackerbarth et. al (2021) further identified that in addition to the failure to understand the philosophical roots of Lean, practitioners were often not adhering to its basic principles or steps. A key message within much of the literature was therefore that there is a lack of understanding of Lean Six Sigma at a philosophical level (Burke, 2008; Radnor et al., 2012; Stone, 2012; Lawal et al., 2014; Flynn et al.,

2018). The original intent and purpose of Lean were however shown to have potential synergies with the philosophical intentions of person-centredness (Teeling, Dewing & Baldie, 2020). Consequently, the aim was to identify, explore and understand Lean Six Sigma's contribution to person-centred care and person-centred cultures through empirical testing of the programme theory using realist evaluation (chapter four). Research participants adjudicated the findings of the CMOc, 'Lean Six Sigma and Staff', identified from the realist review (chapter two). They identified different contexts (C) which, with key mechanisms (M), were considered to trigger a range of outcomes (O) where the intervention of the UCD Lean Six Sigma education and training programme was introduced. Consistent with realist evaluation methodology, participants confirmed, refuted or refined the programme theory (Pawson & Tilley, 1997) and identified what, in their experience, facilitates or hinders the effectiveness of the intervention to deliver anticipated outcomes (Dobson & Fitzgerald, 2005). This gave rise to three distinct embedded CMOcs:

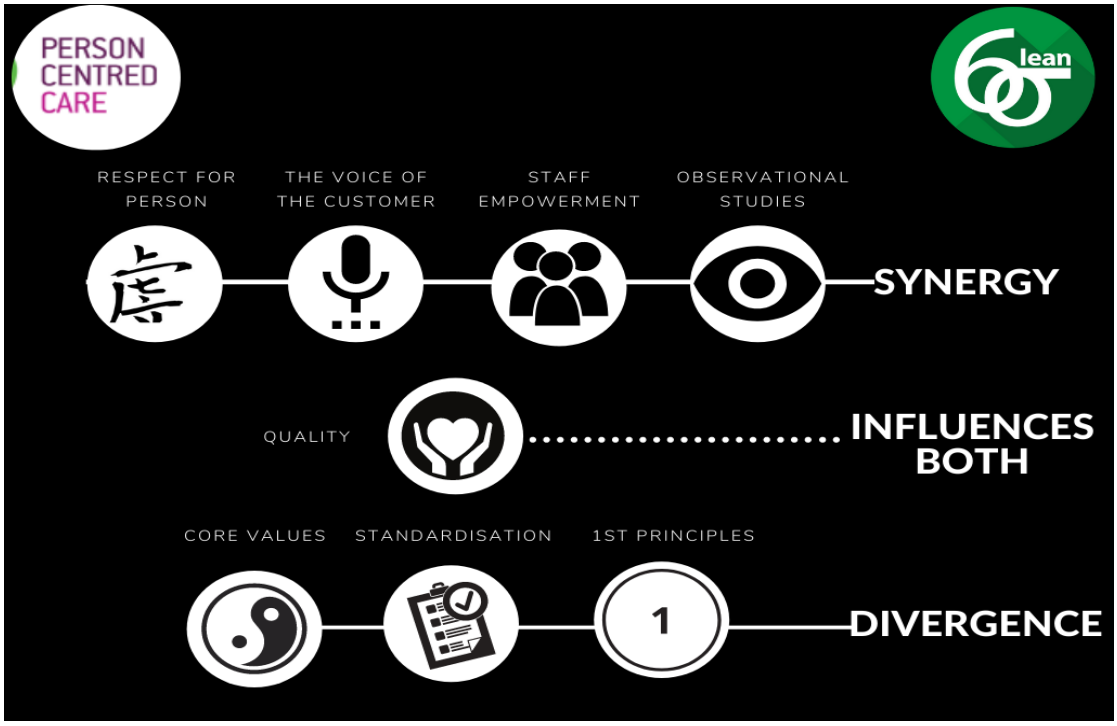
CMOc1. Aspects of organisational culture (Chapter 5)

CMOc2. The organisation's receptivity to Lean Six Sigma (Chapter 6)

CMOc3. Participants' self-perception as Lean Six Sigma practitioners (Chapter 7)

Participants' use of the 'Synergies and Divergences between Lean Six Sigma and Person-centred Care and Cultures' model (figure 8.1), synthesised from the realist review, enabled them to locate the synergies and divergences, as well as one influencer – quality, between these CMOcs and person-centred care and cultures.

Figure 8.1 Synergies and Divergences between Lean Six Sigma and Person-centred Care and Cultures



Source: Taken from Teeling, Dewing and Baldie (2020, p.19)

The findings (chapters five, six and seven) showed the extent to which the research aim was achieved. This chapter discusses the findings in relation to the programme theory locating them within the existing literature on Lean Six Sigma, person-centred care and person-centred cultures (section 8.2). The implications of the findings for future Lean Six Sigma practice, policy, education and training, and research (section 8.3) are then considered, detailing the outputs of this research and plans and recommendations for further dissemination of the methods used and the study findings. The strengths, limitations and delimitations of the study are then discussed to enable the reader to judge the relevance and significance of the research findings and recommendations (section 8.4). Finally, there is reflection on the philosophical framework of critical realism and the use of realist review and evaluation (section 8.5) before closure (section 8.6).

8.2 Findings and the Programme Theory

8.2.1 Introduction

In this section the findings in relation to the initial programme theory and the aims of this study are discussed. As discussed in chapter three, a programme theory is a pre-requisite of realist evaluation methodology (Westhorp, 2014) intended as a set of explicit or implicit assumptions about how the programme should be organised and why it is expected to work (Chen, 2005). Chapter three discussed how critical realism operates as a 'mid-range' theory (Merton, 1968). Jagosh (2019) describes mid-range theory as theory that is not so theoretical as to be wholly abstracted from the workings of programmes at a proximal, 'on the ground' level, yet not so specific as to pertain only to the effect of one programme in a tightly bounded practice context. Mid-range theory attempts to understand interventions (in this case the Lean Six Sigma education and training programme) at a level between their origins at a distal concept level (e.g., curriculum development in higher education) and the proximal level (e.g., specific practice areas at the study site). The focus is on the how the concept is realised or enacted across specific contexts and its impact on the people (here, staff at the study site) who are affected by it. According to Wong (2017), mid-range theory is at the correct level of abstraction to be 'useful' and 'testable'.

The aim of this study was to evaluate and 'test' the programme theory, 'Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD Lean Six Sigma education and training programme'. Pawson and Tilley (2004) suggest that, when using realist evaluation, the findings (theories) should have the following characteristics:

- Configurational: Theories illustrate the combinations of related attributes that need to be in place for a programme to be effective. The development of the three distinct embedded CMOcs (chapters five, six and seven) do this.
- Mid-range: Theories are invested with concepts that link to other programme theories and therefore have the potential for transferability. The programme theory is sufficiently detailed for it to be potentially transferable to other

contexts and to guide further research in the area of Lean Six Sigma and person-centred care and cultures.

- Adjudicationist: Findings obtained should provide an opportunity for adjudication in order to find alternative explanations for the theory, what Pawson and Tilley (2004, p.17) term 'sorting and sifting'. This 'sorting and sifting' took place via participants' iterative adjudication of the contextual factors, mechanisms and outcomes as they were developed (chapter four).

There now follows discussion on how the developed CMOcs, presented in chapters five, six and seven, map to the Synergies and Divergences model (figure 8.1), which was developed from the realist review (chapter two). The mapping is depicted in figures 5.7, 6.6 and 7.6. The discussion allows the researcher to ascertain where the findings validate the initial programme theory and also where they may require adjusting or further inquiry.

8.2.2 Synergy: Respect for Persons

In chapter two, there was discussion on how the belief in respect for persons inherent in the concept of Kaizen is synergistic with the collaborative, inclusive and participatory principles of person-centredness (Manley et al., 2014; Dewing et al., 2015). Participants found the approach to the use of Lean Six Sigma within the study site to be synergistic with the concepts of respect for persons and staff empowerment, themselves enablers of person-centred cultures (McCormack et al., 2010). Joosten et al. (2009) note that the development of staff through support and respect is important for their engagement with Lean Six Sigma, and participants advised they felt both supported and respected. The approach of giving to employees through opportunities for development through the Lean Six Sigma education and training programme, rather than getting something from them, such as more productivity (Veech, 2004) is synergistic with the person-centred value of respect for persons, which is enabled by empowering cultures (McCormack et al., 2010). Joosten (2009) notes the importance of linking process improvement to respect for the individual. Participants found that in their experience Lean Six Sigma is synergistic with the concept of respect inherent in Lean (Liker, 2004) and the person-centred concept of respect for persons

(McCormack, 2003). The focus of the Lean Six Sigma education and training programme on both patients' and staff's experiences of improvement was seen by participants as synergistic with respect for persons, as empowering staff and as recognising the need for a principles and values-based approach to improvement (Suárez Barraza et al., 2011).

In summary, the synergy of 'respect for persons' identified in the realist review was validated by the study participants, graduates of the Lean Six Sigma education and training programme (the intervention). Their experiences of using Lean Six Sigma in their practice at the study site in turn validated the programme theory that Lean Six Sigma contributes to person-centred care and cultures when the contextual factors trigger particular mechanisms as discussed in chapters five, six and seven.

8.2.3 Synergy: The Voice of the Customer

Participants found that Lean Six Sigma enabled them to engage with people, hear their voices (Breckenridge et al., 2019) and try to meet their expectations as customers (Pande et al., 2002; Found & Harrison, 2012). This was facilitated by the use of Lean and Six Sigma quality tools designed to map the customer voice (Rath and Strong, 2002; George et al., 2005). As discussed in chapter two, the voice of the customer approach to understanding customers' requirements is synergistic with person-centred care practices, which utilise observations, narratives, conversations, focus groups and workshops (Dewing et al., 2015). The significance of open and clear communication for participants, clearly communicating the benefits of Lean Six Sigma work at the level of the department, unit, ward or practice area was found to be a cornerstone of their Lean Six Sigma practice. This is supported in the literature by the call for more open communication with staff (Arthur, 2016) and is synergistic with the concepts of voice of the customer. The use of Lean Six Sigma methodology actively sought to capture practitioners and their colleagues input, giving them a voice in the nature and direction of improvement projects, and empowering them (Lipley, 2009).

In summary, the synergy of 'voice of the customer' identified in the realist review was validated by the study participants, graduates of the Lean Six Sigma education and training programme (the intervention). Their experiences of using Lean Six Sigma in their practice at the study site in turn validated the programme theory that Lean Six

Sigma contributes to person-centred care and cultures when the contextual factors trigger particular mechanisms as discussed in chapters five, six and seven.

8.2.4 Synergy: Staff Empowerment

Laloux (2014) notes that, when there is no consensus on how Lean is practised, hierarchical structures and behaviours may emerge. A command-and-control approach may then arise, and Lean will be viewed only at its basic level as a set of decontextualised, technical improvement tasks. Laloux (2014) sees this as antithetical to a culture of empowerment and potentially leading to a top-down management style. Additionally, and of relevance to this research, where a command-and-control structure exists, the needs and the preferences of the individual and respect for persons, key determinants of person-centredness, are unlikely to be taken fully into account (McCormack, 2003; Moore et al., 2016). In this study it has been shown that this was not the experience of the study participants. At the study site, it was found that staff were open to new ways of working when there was an integrative and distributive approach to Lean Six Sigma that was well communicated and supported by the availability of competent and accessible Lean Six Sigma practitioners. These factors contributed to a culture of empowerment and employee motivation which Laloux (2014) claims builds consensus on the most effective use of Lean. These factors can also be seen as 'humanising' process improvement, which is a key context for any successful improvement process (Breckenridge et al., 2019). They also acknowledge the essential requirement of active staff engagement and empowerment in any quality improvement strategy (Watt et al., 2009). Staff empowerment and an organisational culture that encourages improvement are cornerstones of Lean deployment in healthcare (Ballé & Regnier, 2007) and are synergistic with person-centred cultures that encourage and enable staff to engage in ongoing development and quality enhancement (Dewing & McCormack, 2017). The presence of these factors also reflect the concept of 'Kaizen' and its origins in the three main features of the Japanese management philosophy: harmony and loyalty, consensus in decision-making and employment for life (Suárez Barraza et al., 2011).

In summary, the synergy of 'staff empowerment' identified in the realist review was validated by the study participants, graduates of the Lean Six Sigma education and

training programme (the intervention). Their experiences of using Lean Six Sigma in their practice at the study site in turn validated the programme theory that Lean Six Sigma contributes to person-centred care and cultures when the contextual factors trigger particular mechanisms as discussed in chapters five, six and seven.

8.2.5 Synergy: Observational Studies

It has been illustrated that Lean Six Sigma practitioners at the study site visit the areas where the process or work takes place, standing back and observing the work or process, known in Lean Six Sigma as 'Gemba' (Ohno & Bodek, 1988; Womack 2013). It has also been demonstrated how they found it beneficial to their Lean Six Sigma practice. A Gemba walk is always approached from a place of mutual respect and of making thinking better, and in the realist review (chapter two), this was identified as being synergistic with the use of observational studies in person-centred care and person-centred cultures (Dewing, 2015; Teeling, Dewing & Baldie, 2020). The processes involved in both approaches to these real-time observations of people at work (Elgar & Smith, 1994) are virtually identical, with observational studies used within person-centred cultures to measure and evaluate 'where we are now' (Dewing, McCormack & Titchen, 2014).

In summary, the synergy of 'observational studies' identified in the realist review was validated by the study participants, graduates of the Lean Six Sigma education and training programme (the intervention). Their experiences of using Lean Six Sigma in their practice at the study site in turn validated the programme theory that Lean Six Sigma contributes to person-centred care and cultures when the contextual factors trigger particular mechanisms as discussed in chapters five, six and seven.

8.2.6 Influencer: Quality

Throughout the realist review, it was demonstrated that Lean and Six Sigma are quality improvement methodologies suitable for use in healthcare (Womack, 2005; Zidel, 2006; Snee, 2010; Aherne & Whelton; 2010, Graban 2012; Antony, 2012; Williams, 2015; McNamara & Teeling, 2019; Teeling et al., 2019; Teeling, Dewing & Baldie,

2020; Connolly, Teeling & McNamara, 2020; Donegan et al., 2021) but highlighted how interpretations of quality can be influenced by both contextual factors and circumstances, and how the literature differentiated between the idea of results-focused quality as opposed to the concept of a quality culture. McCormack and Watson (2017) suggest that improvement methodologies should aim for improvement through consensus and culture change with continuous improvement and innovation being key components in the development of person-centred care and cultures (Dewing et al., 2015). From the review, quality was identified as an influencer on both person-centred care and cultures, and Lean Six Sigma. Participants identified the approach to Lean Six Sigma work at the study site as having an integrative and distributive approach which was leading to a more person-centred culture. The Lean Six Sigma education and training programme had contributed to this integrative and distributive approach to continuous improvement that sought to understand what staff, patients and their families considered to be important in care delivery; that is, what was, in Lean Six Sigma terms, critical to quality (Snee 1999, 2010; Antony 2012). This is consistent with participants' views that the study site is receptive to person-centred approaches to care and, through the Lean Six Sigma education and training programme, they are coming to recognise that measurement and metrics are not the only, or even most important, components of a quality culture (McCormack, 2017). This suggests that, although quality is currently seen as an influencer on both Lean Six Sigma and person-centred cultures, over time a shared interpretation could evolve so that it can be clearly identified as a synergy. It is therefore a recommendation of this study that the classification of Quality as an 'influencer' merits further inquiry.

8.2.7 Divergence: Core Values

In the realist review (chapter two), it was discussed how value can be seen in a wider context in person-centred care with a focus on patients, families and staff and social values, whereas Lean focuses on the value created by improving processes (Williams, 2015). During the evaluation, participants acknowledged this difference in the understanding of value and the divergence that exists. However, it was found that participants' personal understanding as Lean Six Sigma practitioners echoed the wider context of valuing people and appreciating their core values as opposed to the narrower

perception of value as that arising only from a particular process improvement, which participants indicated was the view of some staff and colleagues at the study site. Participants' understanding of value can potentially more closely align Lean Six Sigma practice to the first principles of person-centred care that seek to clarify people's beliefs and values (William, 2015). This broader understanding of value goes some way to addressing the divergence in first principles and core values of Lean Six Sigma and person-centredness, and to the identified lack of fidelity to Lean's original principles, steps, intent and purpose (Radnor et al., 2012; Stone, 2012; Burgess & Radnor, 2013; Lawal et al., 2014; Flynn et al., 2018 Wackerbarth et. al., 2021).This suggests that, although a divergence was identified in the realist review and confirmed by participants in the realist evaluation, the different conceptions of value can be reconciled and brought into closer alignment through the intervention of the Lean Six Sigma education and training programme. Although more research is required, if this divergence were reconciled, it would potentially demonstrate another synergy between both methodologies. This would further validate the programme theory that Lean Six Sigma delivered through the intervention of the Lean Six Sigma education and training programme has a positive influence on person-centred care and cultures at the level of the study site.

8.2.8 Divergence: Standardisation

In the realist review (chapter two) it was identified that there is potential for rigid insistence on standardisation when using Lean Six Sigma. It was shown that this may be reflected in the variation in the use of the principles and steps of Lean (Wackerbarth et.al., 2021), the use of a specific small set of tools or techniques (Radnor et al., 2012) and/or the variation in Lean application (Burgess & Radnor, 2013). Participants agreed that there was a dichotomy between the need for process standardisation and their wish to deliver more holistic individualised care. However, the Lean Six Sigma education and training programme facilitated the ongoing reconciliation of this divergence in understanding of the role of standardisation by developing staff versed in the theory and practice of improvement methodologies who recognise and appreciate the requirement for process variations (Deming, 2000), when such variation may be in the patient's best interests. Participants indicated that they had achieved

outcomes that enabled them and their colleagues to further their professional development, spend more time with their patients, and work together as empowered and valued teams of practitioners in collaborative, inclusive and participatory ways to plan future improvements (Aherne, 2007; Lipley, 2009; Deihl, 2011; Graban, 2012; Marriot-Statham et al., 2018). They felt that the Lean Six Sigma education and training programme enabled practitioners using Lean Six Sigma and person-centred methodologies to provide person-centred, holistic and individualised care (Morgan & Yoder, 2012), judging when patient care requires diversity (Saurin, et al., 2013), while recognising that process standardisation can be useful and benefit patient outcomes (McGrath et al., 2019). Although more research is required, if this divergence were reconciled, it would demonstrate another synergy between both methodologies. This would further validate the programme theory that Lean Six Sigma delivered through the intervention of the Lean Six Sigma education and training programme has a positive influence on person-centred care and cultures at the level of the study site.

8.2.9 Divergence: First Principles

The realist review (chapter two) discussed how Lean does not fully consider the complexity of social interactions and dynamics in healthcare settings (Black, 2009, Joosten et al. 2009). In the realist evaluation, participants confirmed the divergence between the concept of understanding value as a first principle of Lean (Williams, 2015) and the imperative of person-centred care to attend to professional competence, to commit to ethical practice and to clarify beliefs and values (William, 2015). Participants identified gaps between colleagues' understanding of the first principles of both Lean and Six Sigma, and how they relate to person-centred care and cultures. This again links to the findings of the realist review (chapter two) which illustrated a lack of awareness of Lean as a management philosophy as opposed to a set of quality improvement tools (Burke, 2008; Radnor et al., 2012; Stone, 2012; Lawal et al., 2014; Flynn et al., 2018, Wackerbarth et al., 2021). Participants' felt that their own presence as competent Lean Six Sigma practitioners from the organisation was as an important way to reconcile this divergence. Participants felt that, by developing staff versed in the theory and practice of improvement methodologies (Deming, 2000), the Lean Six Sigma education and training programme facilitated a move from a more technical to

a more person-centred approach to change. Although more research is required, if this divergence were reconciled, this would further validate the programme theory that Lean Six Sigma delivered through the intervention of the Lean Six Sigma education and training programme has a positive influence on person-centred care and cultures at the level of the study site.

8.2.10 Conclusion

In this section, it has been discussed how the findings of the study validated the programme theory 'Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD Lean Six Sigma education and training programme'. It has shown how, through the use of critical realism, the question *whether, to what extent and in what ways, Lean Six Sigma in healthcare contributes to person-centred care and cultures* has been addressed. The mapping of the CMOcs identified in chapters five, six and seven to the Synergies and Divergences model (figure 8.1) synthesised from the realist review (chapter two) speaks to an organisation that is receptive to new and creative ways of working, and to an innovative model of Lean Six Sigma that can enhance efficiency and develop person-centred cultures (Teeling, Dewing & Baldie, 2020). This model of Lean Six Sigma encourages staff self-development (Antony et al., 2007; Joosten et al., 2009; Drotz & Poksinska, 2014; Mårtensson et al., 2019; McNamara & Teeling, 2019), developing employees through organisational support, respect and access to education (Schattenkirk, 2012; Joosten et al., 2019). Such a model would enable Lean practitioners to address and reconcile divergences between Lean Six Sigma and person-centred practice in relation to core values and first principles.

In this study, participants were clear that the Lean Six Sigma education and training programme had contributed to what Hochman et al. (2016) term a 'culture of quality' in their organisation. This is congruent with Kaplan et al.'s (2014) argument that Lean Six Sigma deployment is not just about the quality improvement itself but about creating a supportive institutional culture (Andersen et al., 2014; Graban, 2016). This is synergistic with the cultural aspect of person-centredness that promotes and incorporates care (Dewing & McCormack, 2016). These findings speak to a model of

improvement that recognises the need to combine Lean Six Sigma with the principles of person-centredness to achieve efficiency and to preserve the autonomy of staff (Drotz & Poksinska, 2014; Mohd Amran et al., 2020), patients and families. This envisions a model of Lean Six Sigma practice that facilitates a culture of empowerment (Laloux, 2014) and is synergistic with person-centredness (McCormack, 2003; Moore et al., 2016). This model of Lean Six Sigma has as its basis an understanding that Lean Six Sigma is more than a set of quality improvement tools and techniques (Burke, 2008; Radnor et al., 2012; Stone, 2012; Lawal et al., 2014; Flynn et al., 2018, Teeling, Dewing and Baldie, 2020; Wackerbarth et al., 2021). Rather it recognises that the intent of Lean is to firstly value people, seeking to clarify their beliefs and values (William, 2015) and shows an understanding of Lean as a philosophy of life (Imai, 1986; Wittenberg, 1994; Gondhalekar et al., 1995).

In summary, participants' adjudication of the CMOcs and their mapping to the Synergies and Divergences model (figure 8.1), as illustrated in figures 5.7, 6.6 and 7.6, and discussed in chapters five, six and seven, indicated that the intervention of the Lean Six Sigma education and training programme contributed to person-centred care and cultures when the contextual factors triggered particular mechanisms at the study site.

There now follows a discussion of the implications of the findings for future Lean Six Sigma practice, education and training, and research.

8.3 Final Research Outcomes, Recommendations, Implications for Practice and Further Research

The aim of this research was to evaluate the programme theory, 'Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD Lean Six Sigma education and training programme', by asking *whether, to what extent and in what ways, Lean Six Sigma in healthcare contributes to person-centred care and cultures*. This discussion chapter, has illustrated how the findings of the realist review (chapter two) and realist evaluation (chapter four), supported by findings from research participants' Lean Six

Sigma projects (appendix 4.1), have demonstrated the positive contribution of Lean Six Sigma to person-centred cultures, highlighting the synergies and divergences between them, how the divergences can be reconciled, and the influence of quality on both methodologies (figure 8.1). There now follows a summary of the contribution of this research by discussing key outcomes of the study. Each outcome indicates the contribution to wider theory, research, policy and practice as relevant.

Research Outcome 1
Relevant to theory, research, policy and practice

Prior to this study little research was found into the complexities of introducing Lean Six Sigma into healthcare contexts in which the use of person-centred approaches is increasing. As a result, the contexts and mechanisms in and through which Lean Six Sigma education and training programmes influence healthcare staff and person-centred practice were poorly understood. This research has identified coherence in the underlying philosophy, intention, method and outcomes of Lean Six Sigma and person-centred approaches to process improvement. This contributes to researchers, policy makers and practitioners awareness and understanding of the origins, purpose and methods of Lean Six Sigma and should inform its introduction and implementation in practice. Whether or not such an understanding exists will determine its impact on the development of person-centred care and cultures.

Research Outcome 2
Relevant to theory, research, policy and practice

Based on the findings of the realist review and realist evaluation, four synergies and three divergences between Lean and person-centredness as well as one influencer, quality, that influenced both methodologies were discovered and explored. Alignment of the three CMOcs, aspects of organisational culture, the organisation's receptivity to Lean Six Sigma and participants' self-perception as Lean Six Sigma practitioners, resulted in an increased understanding of whether, how and in what ways the Lean Six Sigma education and training programme influenced person-centred practices and cultures. The research has indicated where synergies can be maximised and divergences reconciled to improve implementation and enhance methodological coherence. It has also identified that divergence occurs mainly at the level of Lean Six

Sigma implementation, particularly where it has been wrenched from its original purpose and underpinning philosophy and focuses only on process standardisation and efficiency gains, with even then wide variance in the application of the implementation of Lean (Radnor et al., 2012; Burgess & Radnor, 2013). As discussed, this situation arises when Lean Six Sigma practitioners are unaware of, pay little attention to, or fail to understand Lean's philosophical roots (Imai, 1986; Wittenberg, 1994; Gondhalekar et al., 1995; Radnor et al., 2012; Lawal et al., 2014; Flynn et al., 2018; Teeling, Dewing & Baldie, 2020; Wackerbarth et. al, 2021). This failure to recognise, or to have fidelity to (Wackerbarth et. al, 2021) Lean's philosophical roots and its original intention to clarify people's beliefs and values (William, 2015) as a prerequisite step to improvement is an important finding with implications for theory, research, policy and practice. Knowledge of Lean's philosophical roots, with its focus on valuing people and their values from the start, were however shown to have potential synergies with the philosophical intentions of person-centredness (Teeling, Dewing & Baldie, 2020). Coherence in philosophy, intention, methods and outcomes exists between Lean Six Sigma and person-centred approaches. Their combined use to improve patient and staff experiences is not only possible but may also be desirable. The knowledge of the synergies that exist between both Lean Six Sigma and person-centred methodologies and how their divergences may be reconciled could impact the design and direction of further theory, education and research in this area and inform future healthcare improvement policy. Importantly, it could also enable Lean Six Sigma practitioners internationally to work in ways that support the development of quality, person-centred care that takes account of the outcomes for, and experiences of, patients, their families and staff.

Research Outcome 3
Relevant to theory, research, policy and practice

A new person-centred approach to adjudicating CMOcs was developed that makes a new contribution to realist evaluation. As this study was investigating person-centredness, it was determined that person-centred values and principles would guide the design and conduct of the realist evaluation. Hence, person-centred principles and realist evaluation methodology together informed the design and implementation of

the study methods. The study has shown that whilst adhering to the principles and rigour of realist evaluation, the use of Person-centred principles with their inherent critical creativity (McCormack et al., 2014) are appropriate for data collection and can be threaded through a realist evaluation approach (Cook, McConnell & Teeling, 2021). Incorporating person-centredness resulted in a new way of adjudicating CMOcs and novel methods of working with research participants to collect and analyse data for the realist evaluation. This outcome therefore makes a contribution to theory and research in the areas of both person-centredness and realist evaluation. This in turn can influence the use of both in future practice.

These outcomes lead to the following recommendations:

Recommendation 1

The design and delivery of the curriculum of the UCD Lean Six Sigma education and training programme (the intervention) should be explicitly informed by the outcomes to ensure that Lean Six Sigma practitioners are aware of the coherence in the underlying philosophy, intention, method and outcomes of Lean Six Sigma and person-centred approaches to process improvement. The outcomes of this study also have implications for persons who are lecturers or researchers in quality and process improvement beyond the immediate research site, who may wish to inform their own work and subsequently their student practitioners with the identified coherence. It is also relevant to quality improvement practitioners in informing their own awareness and understanding of both person-centred and Lean Six Sigma methodologies.

Recommendation 2

The adoption of person-centred approaches to the use of Lean Six Sigma to develop person-centred cultures should be used in all quality and improvement work at the study site. As discussed throughout this thesis, it was identified that the divergence between Lean Six Sigma and person-centred approaches to improvement occurs mainly at the level of Lean Six Sigma implementation (Radnor et al., 2012; Burgess & Radnor, 2013), however, the outcomes have illustrated that an understanding of the coherence in the philosophical roots of both could enable Lean Six Sigma practitioners to work in ways that support the development of quality, person-centred care. This will

be of interest to theorists, researchers, policy makers and practitioners beyond the immediate study site, as approaches to improvement move beyond application, implementation or translation of research evidence, and towards development of non-traditional ways of being, knowing and doing that enables blending of knowledge (Dewing, 2016).

Recommendation 3

There is need for further research on the synergies that exist between Lean Six Sigma and person-centred care and cultures, and how their divergences can be reconciled to enable Lean Six Sigma practitioners to maximise their contribution to improving quality in healthcare. This research could build on this study's findings and enable further understanding of how Lean Six Sigma and person-centred methodologies are synergistic, and where to narrow the identified divergence. This research will impact on theory and practice, recognising that different kinds of knowledge are used to improve practice, and develop the practitioners professional identity (Dewing and McCormack 2017).

Recommendation 4

The use of person-centred principles to inform the adjudication of the CMOcs has led to novel methods of collecting and analysing data for realist evaluation that enact person-centredness in working with research participants. These methods can be adopted by realist evaluators who wish to work in a person-centred way whilst still adhering to adhering to the principles and rigour of realist evaluation.

In addressing these recommendations, the following actions have already commenced:

Action 1

To address recommendations one and two, a new UCD module, Person-Centred Care for Quality in Health Systems, has been developed in collaboration with colleagues in the health systems subject area and will be incorporated into the Lean Six Sigma pathway of the MSc in Leadership, Innovation and Management for Healthcare from January 2021. In addition, the initial findings of this study have been presented to

colleagues at the study site and Lean Six Sigma practice groups using person-centred approaches to improvement have been established.

Action 2

To address recommendations one, two, three and four, research dissemination has been ongoing. The realist review (chapter two) informed a paper in the International Journal of Research in Nursing in January 2020 (Teeling, Dewing & Baldie, 2020). The research design and methods (chapters three and four) are presented in chapter eleven of a new book on person-centred nursing research (Cook, McConnell & Teeling, 2021). Both chapters two and four informed a presentation at the 36th Annual Conference of the International Society for Quality in Healthcare in Cape Town in October 2019. Further dissemination is outlined in table 8.1, the research dissemination plan.

Action 3

To address recommendation three, as part of the realist review (chapter two), three initial CMOcs relating to Leans Six Sigma and Patients, Staff and the Organisation were developed. The focus of this study was Lean Six Sigma and Staff. Plans for post-doctoral research into the remaining two CMOcs relating to patients and organisations are in place.

Research Dissemination and Pathway to Impact

To highlight the research dissemination plan use has been made of the Vitae Researcher Development Framework (Vitae, 2010) (Appendix 8.1). The framework facilitates researchers to plan and evaluate their professional development and has been found to be useful for research career development (Bray & Boon, 2011). This framework has been useful in planning research dissemination, drawing on Domain D, which provides guidance on research engagement, influence and impact. Aspects of Domain D are outlined below:

Domain D2

The researcher is able to:

- engage in knowledge exchange and debate with a range of audiences
- develop skills in using a range of communication means, including a web-presence
- understand the process of publication and produce publishable material
- identify a diverse range of publication outlets.

Domain D3

The researcher is able to:

- contribute to teaching and research supervision at a range of levels of education
- understand the value of, and engage in, local public event opportunities
- understand the wider policy context and present findings in a policy appropriate format.

The researcher demonstrates:

- an awareness of the impact of research on wider society and culture and an awareness of the impact of society and culture on research
- a broad understanding of the national and international context of the research.

The relevant aspects of Domain D are mapped to a research dissemination and pathway to impact plan (table 8.1) to illustrate progression and awareness as a researcher.

Areas for further study

Dixon Woods (2019) suggests that the study of quality improvement methodologies in healthcare contributes to, and is important in developing an evidence-base and in looking at more than improvement interventions alone. This research has contributed to this evidence base, and can further contribute through the identification of the following areas for further study:

- The immediate area for further study are the two foci of research identified within the realist review (chapter two), Lean Six Sigma and Patients, and Lean

Six Sigma and the Organisation. As discussed initial CMOcs for these have already been developed from the realist review.

- Another area for study is to further explore the reconciliation of the divergences identified between Lean Six Sigma and person-centred care and cultures (figure 2.18), discussed throughout this thesis.
- Potential exists to further research and understand why there has been the drift of Lean from its philosophical roots to an understanding of its use solely as a set of quality improvement tools.

Table 8.1 Research Dissemination and Impact Plan

ISSUE: LACK OF RESEARCH INTO THE COMBINED USE OF LEAN SIX SIGMA AND PERSON-CENTRED IMPROVEMENT SCIENCES IN HEALTHCARE, AND CONSEQUENT POOR UNDERSTANDING OF THE MECHANISMS AND PROCESSES THROUGH WHICH LEAN SIX SIGMA EDUCATION AND TRAINING PROGRAMMES INFLUENCE HEALTHCARE STAFF AND PERSON-CENTREDNESS IN PRACTICE	**STAKEHOLDERS:** 1.QUALITY IMPROVEMENT (QI) PRACTITIONERS 2.HEALTHCARE STAFF WORKING WITH BOTH SCIENCES 3.UNIVERSITY STAFF WORKING WITH QI STUDENTS 4.NON HEALTHCARE QI PRACTITIONERS WORKING WITH HEALTHCARE STAFF	CORRESPONDS TO VITAE RDF DOMAINS D2 AND D3
ACTIVITIES	**TIMELINES**	**PROGRESS**
Presentation at 5th Annual UCD Lean Symposium (Dublin, Ireland)	**23rd November 2017**	**Attended by Minister for Health Session audience of 220 36 retweets and 70 twitter engagements Retweeted by Minister for Health's office**
Health Service Executive (HSE) QI talktime webinar (Dublin, Ireland)	**10th April 2018**	**Live audience of 60 286 downloads of seminar to date National QI team undertook Lean training post podcast**
Presentation at 6th Annual Waterford Institute of Technology (WIT) Lean Conference (Waterford, Ireland).	**3rd May 2018**	**Invited to collaborate with the Irish Business and Employers Confederation (IBEC) post this presentation**
Presentation at UCD Person-centred care conference (Dublin, Ireland)	**15th May 2018**	**Session audience of over 100 942 twitter impressions 15 retweets and 98 engagements**
Presentation at 3rd International Integrative Nursing symposium (Galway, Ireland)	**22nd May 2019**	**International Audience - session audience 300+ 121 twitter engagements and 8 retweets Contributed to Chapter 'Integrative Nursing in Ireland' in Integrative Nursing (2019) 2nd edition**
Presentation at 36th International Society for Quality in Healthcare Symposium (Capetown, South Africa)	**22nd October 2019**	**Feedback 4.8 out of a possible 5 stars as reviewed by audience Following this I was an editor and contributor to a special supplement of the International Journal of Quality in healthcare**
Presentation at 7th Annual UCD Lean Symposium (Dublin, Ireland).	**28th November 2019**	**Invited to report on my provisional findings 330 session attendees 142 twitter engagements and 18 retweets**
Publication with supervision team: 'A Discussion of the Synergy and Divergence between Lean Six Sigma and Person-Centred Improvement Sciences' - International Journal of Research in Nursing.	**11th January 2020**	**Published - draws on chapter two of my thesis.**
Publication with student 'Live well after Stroke' - improving care for patients using a combination of Lean Six Sigma and person-centred approaches - International Practice Development Journal	**18th November 2020**	**Published - illustrates the use of Lean Six Sigma and person-centred approaches to improvement in practice**
Future presentation at Realist 2021 (Dublin Ireland - now virtual due to Covid)	**16th-18th February 2021**	**I have been accepted to give an oral presentation on my research findings and a poster presentation on my research methods**
New UCD module developed with Health Systems colleagues in UCD NMHS43900: Person-Centred Care for Quality in Health Systems	**January 2021**	**Commencing 2021 - designed to inform researchers, practitioners and staff of the coherence between Lean Six Sigma their contribution to Person-centred cultures, based on the findings of this research**
Publication with colleagues: Person- centred Nursing Research: Methodology, Methods and Outcomes. Chapter 11 - Multiple and Mixed Methods Research.	**Due for publication March 2021**	**In publication - draws on chapter four of my thesis.**

This thesis reports the outcome of what is the first study to use realist evaluation to explore the degree and nature of the coherence between Lean Six Sigma and person-centred methodologies in healthcare practice. It makes a significant and distinctive contribution to the field and, therefore, research dissemination has been and will continue to be a priority. As discussed in section 8.3, the study outcomes and recommendations are relevant to both the study site, and further afield with implications for future theory, research, policy and practice. The study's delimitations and limitations are now discussed.

8.4 Research Delimitations, Limitations and Strengths

This section addresses the delimitations, possible limitations and distinctive strengths of the study.

Delimitation

This study focused on the contribution of Lean Six Sigma to person-centred care and person-centred cultures in a university hospital in Ireland. This was a choice made as the study site was the first hospital in Ireland to have an on-site Lean Academy, a team of service improvers and an accredited Lean Six Sigma education and training programme with its partner university, which, at the time of commencing this study, had been running for a number of years. A decision was made not to focus on the wider population of graduates of the UCD Lean Six Sigma education and training programme nationally, as there was a large pool of interdisciplinary staff available at the study site, and other sites were at different stages of their Lean Six Sigma improvement journeys. The thesis has described in detail the intervention and the context in which participants engaged with it; therefore, Lean Six Sigma and quality improvement practitioners internationally can determine the applicability of the study findings to their contexts.

Limitations

- Only one programme was evaluated, the UCD Lean Six Sigma education and training programme, which has developed over the last six years and is likely to be quite different in its design and development from other Lean Six Sigma

education programmes. However, the research findings offer opportunities for reflection, learning and development for other providers of Lean Six Sigma education that needs to be further evaluated to understand its overall relevance and impact in a range of contexts.

- There was a lack of published research specific to the use of both person-centred and Lean Six Sigma methodologies to draw on for the realist review that underpinned this study; however, the initial programme theory was informed not only by the literature but also through engagement with colleagues using Lean Six Sigma in their practice.
- The participants selected included Lean Six Sigma practitioners from a range of professions who were able to offer diverse insights to enable evaluation of the programme theory. The sampling process (section 4.3.3) may have excluded other professions that may have adjudicated the programme theory differently. However, Wong et al. (2017) acknowledge that in realist evaluation, different groups and subgroups of participants may respond differently to an intervention.
- There was constant awareness of being an insider researcher and of the potential influence on the research and on the willingness of others to participate. Section 4.3.2 acknowledged and discussed this positionality, describing the use of reflexivity within this study to ensure responsible and ethical practice throughout the research process (Williamson et al., 2012; Bolton, 2014). The use of researcher reflexivity enabled engagement in critical self-reflection about any personal biases, preferences and preconceptions (Polit and Beck, 2008). Additionally, the use of reflexivity throughout the study is consistent with best practice for insider researchers that recommends critical reflection is included in the study design (Costley et al., 2010). Although being an insider is here recognised as a limitation, knowing the culture and context did support the provision of a psychologically safe environment for participants.
- Although person-centred principles were used in designing data collection, and prepared the environment to be a 'safe space' (chapter four) it was not possible to anticipate and address all potential factors that may have influenced

participants' responses; for example, socially desirable responses to me as the director of the education and training programme, workload demands, time constraints and the level of stress they may have been under at the time. The process was managed by using reflexivity throughout, both personal and with my supervision team, strengthening self-awareness and the ability to negotiate respectful relationships with participants. Over time I enhanced my capacity to develop 'analytical distancing', thus enhancing reflexivity further (Burns et al., 2012).

- This study, whilst adhering to the principles and rigour of realist evaluation, also used person-centred research methodologies for use in data collection. The potential limitation of using both methods were discussed and defended in section 3.4. However, it was shown that the use of critical creative person-centred approaches enable deep exploration of the research question (Mannay, 2010, 2016 ; McCormack et al., 2014; Kara, 2015). Further discussion of the research methodology is discussed in section 8.5, methodological reflection.
- Only one of the three CMOcs identified was explored from the realist review, 'Lean Six Sigma and Staff'. However, as now discussed this may also be seen as a strength of the research.

Strengths of the Research

- As discussed in chapter two, focusing on Lean Six Sigma and Staff', was a strength in that staff proficiency and knowledge of Lean Six Sigma are mechanisms for patient outcomes and this focus allowed understanding of where and how staff, as the key mediators between the intervention and its outcomes, work with Lean Six Sigma in their everyday practice.
- The study has identified two further foci of research which will contribute to an understanding of the contribution of Lean Six Sigma to person-centred care and cultures: Lean Six Sigma and Patients, and Lean Six Sigma and the Organisation. Initial CMOcs for these have already been developed from the realist review.
- This study is the first to use realist evaluation to evaluate the contribution of Lean Six Sigma to person-centred care and person-centred cultures and is

original in its combined use of person-centred principles and realist evaluation methodology to inform its design and implementation.

- The research also makes a contribution to the debate on the need for healthcare practitioners, managers and leaders to move from evaluating only certain outcomes to more person-centred ways of evaluation.

8.5 Methodological Reflection

Having carried out this research it is evident that this study is the first to use realist evaluation to examine the contribution of Lean Six Sigma to person-centred care and cultures. Chapter three detailed the limitations and strengths of realist evaluation. One criticism was a preoccupation with health outcomes as opposed to wider system outcomes (Herepath et al., 2015); however, this research has looked at the impact of Lean Six Sigma on the experiences of staff, patients and their families, as opposed to a sole focus on certain patient outcomes. The study sought the views of a diverse multidisciplinary group of Lean Six Sigma practitioners to facilitate clarification and refinement of the programme theory, the pre-requisite to sound evaluation (Pawson & Tilley, 1997; Weiss, 1997). Realist inquiry seeks to inform the realist researcher's understanding of the relationships between context, mechanism and outcomes for specific interventions (Newton et al., 2011) and certainly informed an understanding of these relationships for the intervention of the Lean Six Sigma education and training programme.

The person-centred principles that informed the research methods enabled both the researcher and the study participants to develop a shared understanding of the contribution of Lean Six Sigma to person-centred care and cultures. This shared understanding facilitated progression from an initial programme theory to the evidence-based refinement of causative factors (Pawson, 2000, Pawson et al., 2005). This supports the use of realist evaluation as an appropriate methodological choice for this study as it enabled effective evaluation of the programme theory 'Lean Six Sigma can have a positive influence on person-centred care and person-centred cultures if delivered through the intervention of the UCD Lean Six Sigma education and training programme'. Through the realist review, three initial CMOcs were identified and then, in the realist evaluation, one of these, 'Lean Six Sigma and Staff', was adjudicated to

identify the outcomes of the programme theory. Following the realist review, it was clear that how staff interpreted the content and principles of Lean Six Sigma significantly influenced how much attention was paid to person-centredness as a key desired outcome.

As discussed in chapter four, it was found that realist evaluation, despite its continued use to evaluate interventions in healthcare, does not provide much detail on methods of data collection and analysis (Gilmore et al., 2019). For example, although NVivo has been used in realist evaluations (Marchal et al., 2010; Maluka et al., 2011; Douglas et al., 2010), details of how it is used are not specifically discussed (Dalkin et al., 2015). This was a catalyst for reflection on the choice of methodology and, as this study was investigating person-centredness, informed the decision to use person-centred values and principles to conduct the realist evaluation. Available published work on realist interviews guided the use of semi-structured realist interviews, which advocate a 'teacher-learner' (sharing knowledge and ideas) approach to interview. Emerging theories were presented to research participants and their confirmation, refinement or refutation of theory, or new theories was actively sought. Therefore, this study used a combination of person-centred principles and realist evaluation methodology in its design and implementation. This facilitated the use of realist principles for what Byng et al. (2005) call organic interpretation. This interpretation recognises the human dimension of process improvement, mindful that it is not an invariable state but, as a continuous process, requires adaptation to context rather than a universal approach (Rees et al., 1996; Syrett and Lammimam, 1997).

Chapter four set out the methods of the testing or adjudication of the programme theory, the findings of which were presented in chapters five, six and seven. As discussed in chapter three, realist work requires an understanding of key aspects of social science, including causation, the nature of the social world and the stratification of social reality (Pawson, 2006). Critical realists recognise that this stratification speaks to three specific domains: the domain of the real (the underlying causal mechanisms), the domain of the actual (the intervention and the actions and responses to which it gives rise), and the empirical domain (changes that are observed) (Wilson & McCormack, 2006; Bhaskar, 2008). The programme theory facilitates an

understanding of these three domains by hypothesising how an intervention is expected to work, accounting for contextual influences and the underlying mechanisms of action (Jagosh, 2019) that realise outcomes.

Wilson and McCormack (2006) suggest that the evaluation of an intervention (in this case the Lean Six Sigma education and training programme) enables the uncovering and analysis of the causal mechanisms operating at the level of the real. Pawson states that this enables the realist researcher to "look beneath the surface in order to inspect how they [causal mechanisms] work" (Pawson, 2006, p. 24). Further, Pawson and Tilley (1997) explain that, because social reality is stratified and different social actors will perceive their own situations and circumstances differently, the researcher (in this case, me) aims to understand the social world as perceived and experienced by these social actors (in this case, the study participants). This study revealed, analysed and presented (through the CMO configurations) the ways in which the actions, interactions and experiences of the Lean Six Sigma education and training programme graduates, and the outcomes they achieved, were shaped by and in turn shaped their social realities at the meso and macro-levels. For example, it has been shown, how this programme with the support of the hospital's Lean academy enabled the graduates (the micro-level), through their Lean Six Sigma practice, to shape the meso-level of the local team, unit or department, creating in turn conditions that increased the likelihood of positive outcomes from future Lean Six Sigma work.

The programme theory attempts to take into account the variables that may contribute most to the success or failure of the programme. In this study, participants adjudicated the programme theory and confirmed, refined or refuted contextual factors, mechanisms and outcomes, identifying synergies, an influencer and divergences between Lean Six Sigma and person-centred care and cultures. The programme theory was validated and this research, in turn, showed that realist theory and philosophy offers a valuable and productive way of understanding the social world.

Due to the lack of guidance in methods for realist research, there was a need throughout of the need to pay attention to the rigour of the study. As indicated in chapter three this was aided by the use of the RAMESES quality standards for peer

reviewers of realist evaluation (Wong et al., 2017). These focus on eight main components of realist evaluation. These are outlined below (table 8.2) and illustrate how this study has followed and adhered to all eight guidelines.

Table 8.2 RAMESES quality standards applied to this study

RAMESES quality standard	Achieved in this study
1.Realist methodology being appropriate	Demonstrated throughout this study.
2.Principles of general causation applied throughout the study	Demonstrated through development and refinement of CMOc (see chapters 2, 5, 6 & 7)
3.Programme theory constructed and refined	Demonstrated throughout this study. Refined programme theory and associated CMOcs can be found in chapters 5, 6 & 7.
4. Design appropriate & ethical guidance followed	Demonstrated throughout and discussed in chapters 3 and 4.
5.Ehtical guidance followed	Yes (see chapter 4)
6.Data collection means suitable for evaluation	Yes, use of a wide array of data including published studies by the study participants and used appropriate realist and person-centred principles to gather and analyse the information gathered (see chapter 4).
7.Appropriate participants to provide data	Yes, participant selection was 20% of available population and was multidisciplinary.
8.Reporting is clear and in line with realist assumptions	Yes, the researcher adhered to critical realism philosophy and structured the study using realist review and realist evaluation.

Source: Adapted from Wong et al. (2017, pp.21-37)

As a final reflection on the philosophical framework refers to Blamey and Mackenzie's (2007) claim that realist evaluation can be both time and resource intensive for the researcher; however, the focus of this study on one specific CMOc from the realist review, 'Lean Six Sigma and Staff' allowed the successful completion of the research within the time and resources available.

8.8 Personal reflection and closure

The process of this doctoral research was twofold, both in relation to the research itself and to my development as a researcher. Personally, it has involved me in a journey of developing my awareness, skills and experiences of Lean Six Sigma, person-centredness, person-centred care and cultures. It has transcended periods of joy and loss, and has come to a close in the changed world of a pandemic. As a joint appointment between the university and the hospital, it has given me the opportunity to work on an area of practice that I continue to be passionate about, process improvement. It has also given me the opportunity to work with research participants whose creative work and transcripts have provided honest and sometimes provocative insights into the challenges and opportunities facing Lean Six Sigma practitioners. This research has, I hope, illustrated how a move to understand and work with the beliefs and values of the staff leading Lean Six Sigma initiatives, as well as the patients and staff they are working with, will ensure increased consideration is given to the complexity of the social interactions in which Lean Six Sigma practitioners and students engage, and empower them to facilitate meaningful change, not only in processes but also in the patterns that support or challenge best practice in person-centred workplace cultures.

> ‘All their life in this world and all their adventures had only been the cover and the title page: now at last they were beginning Chapter One of the Great Story which no one on earth has read: which goes on forever: in which every chapter is better than the one before.’
>
> — C.S. Lewis, The Last Battle

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Appendices

Appendix 3.1: RAMESES Quality standards for peer reviewers of Realist Evaluation reports

RAMESES quality standard
1.Realist methodology being appropriate
2.Principles of general causation applied throughout the study
3.Programme theory constructed and refined
4. Design appropriate & ethical guidance followed
5.Ehtical guidance followed
6.Data collection means suitable for evaluation
7.Appropriate participants to provide data
8.Reporting is clear and in line with realist assumptions

Source: Adapted from Wong et al. (2017, pp.21-37).

Appendix 4.1: Participants' Scientific Posters

Mater Lean Academy
Lean Six Sigma for Healthcare

LOCK, STOCK & FLOW

Maria Creed, Ruth Buckley, Marie Kilduff, Michelle McGuirk
Mater Misericordiae University Hospital (MMUH), Dublin 7.
mcreed@mater.ie

UCD DUBLIN

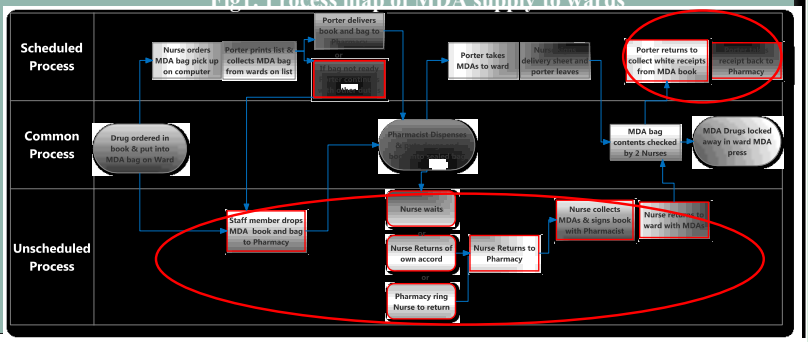
1 DEFINE

Controlled drugs (known as MDAs) are subject to strict legislative control, requiring hand written requisitions, strict documentation management and locked storage. The Mater hospital uses 71 different MDAs, such as morphine and methadone, on a routine basis. This project utilised Lean Six Sigma methodology to improve the controlled drug process in a large teaching hospital.

Problem Statement: When MDAs are required at ward level (if not stocked on the ward) a nurse must leave the patient at unscheduled times to get them from Pharmacy. This impacts patient care and leads to continuous workflow interruption in the Pharmacy.

Goal
To make the controlled drug process more efficient by reducing waste (shown in red) by 25%

Fig1: Process map of MDA supply to wards

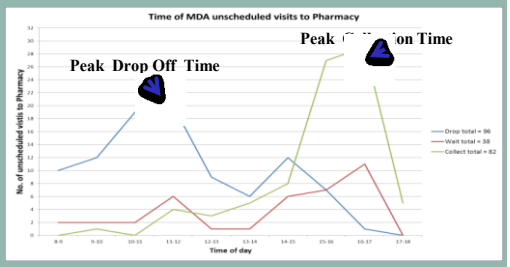


2 MEASURE

A - How often did Nurses leave the wards to get MDAs?

21 Times per day, to get MDAs

B – At what time did Nurses leave the wards to get MDA drugs?



C – How much was the MDA process costing the hospital in Nursing time?

€7.14 Cost per visit

1,313 hrs away from the patient per year

3 ANALYSE

Reasons for using unscheduled process for MDA supply
- Insufficient stock on hand – 27%
- MDA newly prescribed – 25%
- New patient on MDAs- 20%

4 IMPROVE

Following solution brainstorming with stakeholders, a pilot improvement process was tested, before hospital wide implementation in March 2015.

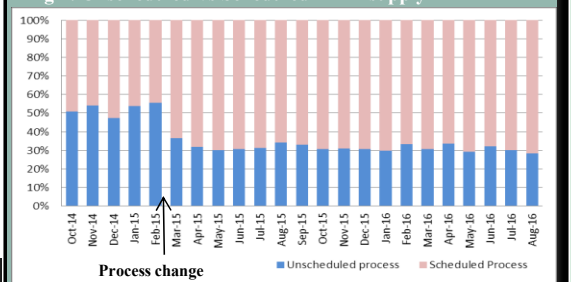
Solutions implemented:
- Scheduled Porter pick up of requisitions increased from 3 to 5 days a week; and removed receipt collection from Porter process
- Later scheduled pick up time for MDA requisitions (10:30 daily) and later subsequent MDA delivery (12:30 daily)

5 CONTROL

How are we doing 18 months later?

Improvement – 40% reduction in Nurses leaving the ward at unscheduled times to get MDAs (exceeded goal of 25%) - a positive outcome for patients, staff and the hospital

Fig 2: Unscheduled vs Scheduled MDA supply



Saving €17,807

Saving 660 Nursing hours

Saving 160 Pharmacy hours

Lessons Learnt
- Stakeholder engagement is invaluable in finding true solutions
- Data, linked to visual management, is essential to drive and sustain improvements
- Keep the patient as the main focus of all Lean healthcare processes

'ASK ME, ASK ME, ASK ME'

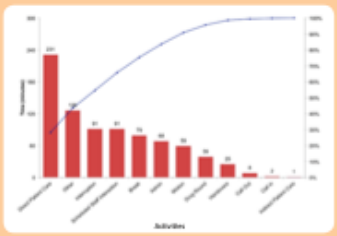
Improving Processes to Decrease Interruptions to Direct Nursing Care

WARDS 4

Project Group: Deirdre Donohoe, Seán Connolly, Heather Gee, Colette Naughton
Aileen Igoe

1. DEFINE & MEASURE PROBLEM

PROBLEM STATEMENT: *'Interruptions to Nursing staff as they carry out daily duties affects direct patient care and can take up to 91 minutes out of a nurse's day. Main difficulties identified include: Time lost from switching tasks / redirecting queries and duplication of requests & information / risk due to interruptions to direct care / information provided which could be accessed elsewhere (Patient Centre) / information sought from incorrect source'*



What's happening on the ward?

Interruptions per day **35***

91 mins of interruptions per **12 hour** shift*

One interruption increases risk of error by **12.7%**

*highest rates during observation study

GOALS & DRIVERS

- **Identify and reduce avoidable disruptions** to nursing care in the context of increasing pressures with decreasing resources
- Associated **reduction in disruption to patient journey and possible reductions in length of stay** - imperative when money follows the patient
- Eliminate **unsafe interruptions**
- Increase **patient, family and staff satisfaction** and **reduce staff frustration**
- Develop alternative **communications** to support interruption reduction

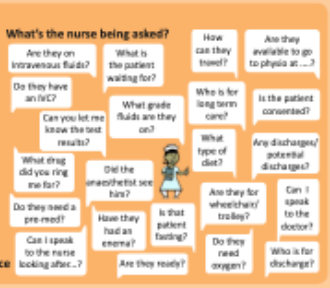
2. ANALYSE PROBLEM

Focus Group, Tallied Telephone Calls to Ward and Interruption Tallies were used as a means of measurement and analysis

5 Day Observation of 12 Hour Nursing Shifts

- Effective communication evident within the nursing team but less evident across the Multi-Disciplinary Team
- Much of patient care co-ordination information is physically held by nursing staff
- The easiest way for other disciplines to access this information is to ask a nurse

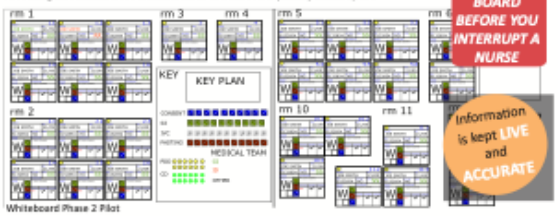
Process Map showed excessive communications were taking place



3. IMPLEMENT IMPROVEMENTS

1. 'PATIENT STATUS AT A GLANCE' BOARD

Providing information for which nurses are most frequently interrupted



Whiteboard Phase 2 Pilot

CHECK THE BOARD BEFORE YOU INTERRUPT A NURSE

Information is kept LIVE and ACCURATE

STEP 1 - UPDATE Board is updated by **designated person** after handover each day

STEP 2 - REGULAR UPDATES Board is updated throughout the day by **person receiving information**

STEP 3 AHPs will update their scheduling on the board

STEP 4 **Medical Team** will use board in their ward round

2. AMENDED ORDER FORMS

Mandatory fields added to referral forms on Patient Centre to provide sufficient information to allow AHP's to prioritise cases

Reduced phonecalls to ward from AHP's for missing information for prioritisation

Original Pilot

3. VISIBLE SCHEDULING

Ward view of scheduled diagnostics on Patient Centre

AHP scheduling will be available on white board

Reduced telephonic contacts regarding scheduled GI procedures Longer term aim for single ward view for daily scheduled diagnostics

NEXT STEPS

OCT 2013 4 week Pilot Phase 2

NOV 2013 Feedback from nursing & Medical Team

NOV 2013 Remeasure baseline data

SAVINGS

TARGET INTERRUPTION REDUCTION OF **27%** **87 MINUTES** (on average) OF NURSING TIME RELEASED PER WARD PER DAY

BENEFITS

- **Information is available** at a glance to all MDT
- Removes requirement to interrupt nurse for **quick information**
- Potential to **release time** for direct nursing care
- Reduced associated **risk** to patient from disruption
- **Improved communication** for a smoother patient journey

SPONSORED BY

MATER LEAN PROGRAMME

Acute Stroke Thrombolysis at the Mater
Door To Needle Project (DTN)

1 DEFINE:

Globally stroke is the second leading cause of death and is leading cause of acquired adult disability. Intravenous Thrombolysis (IVT) with alteplase (tPA) is the only proven drug therapy for acute stroke and it reduces disability when administered within 4.5 hours of stroke onset. This treatment is highly time sensitive in terms of its effectiveness. It has been estimated that 2 million brain cells die during each minute delay in starting therapy. 'Time is Brain'! International guidelines suggest a target median DTN of 60 mins or less. In the USA, this is only achieved in 25-30% of patients. Between 2007-2013, median DTN at the Mater was 75-80 minutes.

2 MEASURE AND ANALYSE:

Historic DTN Stroke registry data from 2007 to 2013 was analysed. A "process time step survey" was undertaken over a 12 week period to identify the processes involved from the time the patient arrival in ED to start of IVT enabling barriers to rapid treatment.

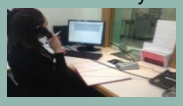
The following barriers were identified:

- Delay in registering patient details
- Delay in ordering CT/bloods
- Delay in CT performance
- Delay in blood processing
- Delay in locating phlebotomy equipment and assessment documentation
- Delay in Stroke Consultant notification and out of hours Stroke Consultant assessment

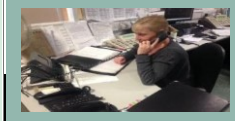
3 IMPROVE

The following solutions were identified and incorporated in to a revised Acute Stroke Thrombolysis

Ambulance Pre-Notifies Hospital



Introduction of a pseudo-Medical Record Number has allowed pre-ordering of CT and bloods prior to the patients arrival to ED.



Stroke Consultant, Stroke Nurse and Registrar are Pre-Notified.

Use of Telemedicine during out-of hours

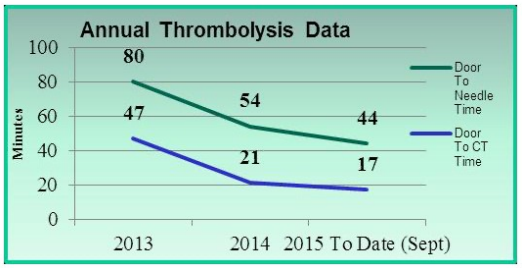
The FAST positive patient is taken directly to the CT scanner in ED upon arrival in the Resus area. Rapid patient assessment now takes place in tandem with CT scanning.

Prepared Stroke pack

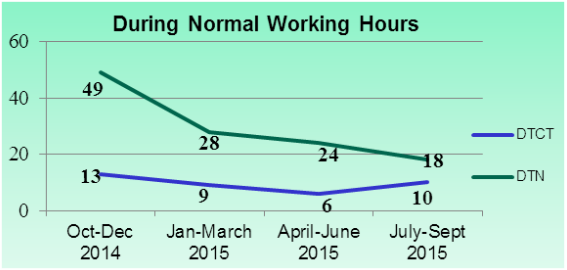
Pre-Stocked IV tray in CT

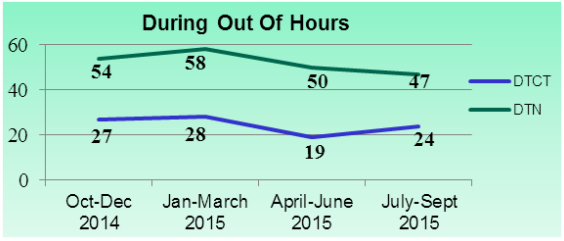
Rapid Laboratory Testing of Bloods

4 CONTROL



45% DECREASE IN DOOR TO NEEDLE TIME
64% DECREASE IN DOOR TO CT TIME





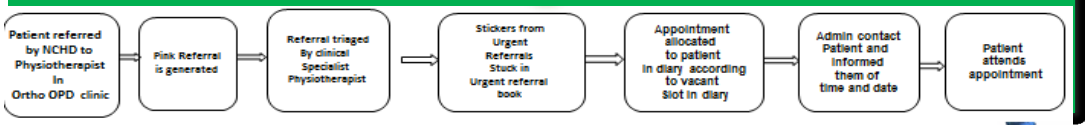
Mater Lean Academy
Lean Six Sigma for Healthcare

‘Let’s Get Physio’

Ruth Greene (CNM II) Karen O’ Sullivan (Senior Physiotherapist) Deirdre Shanahan (Administration Team Manager)
Mater Misericordiae University Hospital (MMUH), Dublin 7

1 DEFINE

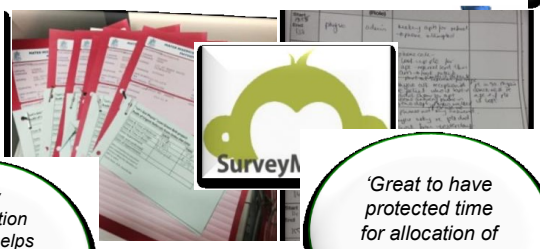
The process for allocation of urgent and routine physiotherapy appointments for those patients referred from various clinics has evolved organically over a number of years and become inefficient. It has become person rather than process driven and entirely paper based.



2 MEASURE

Measurement of the problem took the form of:

1. Data collection form
2. Voice of the customer questionnaire: Qualitative & Quantitative
3. Gemba walk
4. Focus Groups



‘Diary organisation System ‘helps with phone and in-person queries’

‘Great to have protected time for allocation of appointments’

3 ANALYSE

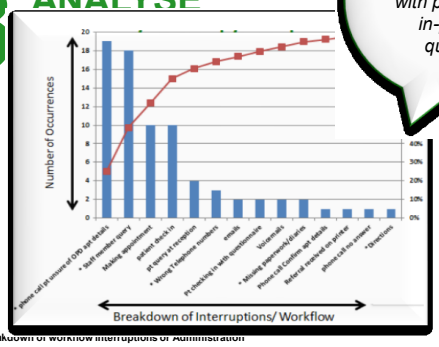


Fig 1 Breakdown of workflow interruptions of Administration

IMPROVE

1. Protected time for tri
2. Protected time for a
3. Diary organisation s
4. Input to SOP & new IMS system

‘Managing change is essential for the organisation as a whole in understanding what the Lean Six Sigma team is doing and accomp

‘Much easier to work in a more organised space’

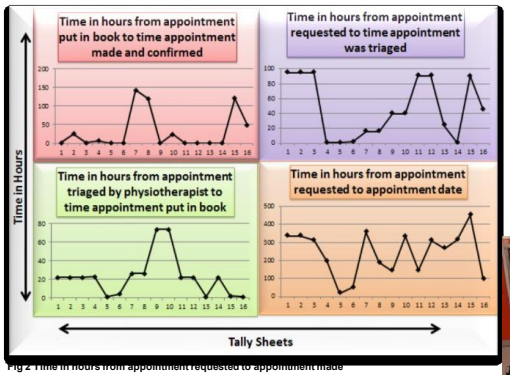
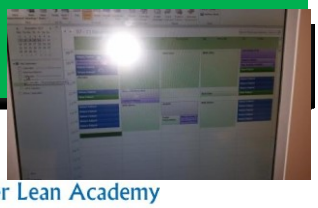


Fig 2 Time in hours from appointment requested to appointment made

5 CONTROL

- Computer on wheels in operation and triage being completed daily
- 3 Physiotherapists move to electronic calendar
- Ongoing process modification and improvement
- Change in culture and practices

Process Driven and not person centered



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Mater Lean Academy
Lean Six Sigma for Healthcare

'OUR DAILY BREAD'

Reducing wasted meals and Improving patient nutrition

WARDS 1

Project Group: [redacted]

1. DEFINE PROBLEM

PROBLEM STATEMENT: *'All Patients on ward are not eating meals prepared in line with specific dietary requirements. Reasons range from patient being off ward for diagnostics or personal reasons/ requiring assistance/ too sick to eat/ meals not prepared as per patient requirement i.e. chopped, pureed/ or food choice. This project aims to identify the root causes for meals being wasted on the wards, to reduce this food waste and address any implications for patient well being and nutrition.'*

Food waste from the wards estimated at **74 tonnes per annum***

*In a waste survey carried out by the MMUH under a Green Healthcare programme in 2011

VOICE OF THE CUSTOMER

"I would like a nutritionally balanced, tasty meal served in a timely manner"

"I expect my nutrition and hydration needs to be met to promote wellbeing and recovery"

"I need someone to help me eat- my food went cold"

VOICE OF THE BUSINESS

"Reduction of food waste and associated costs"

"Meal plans by Dietetics and SLT are implemented"

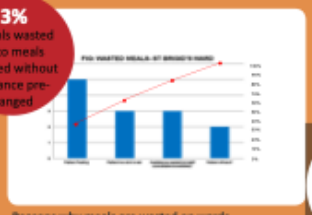
"Patient receives appropriate nutritionally balanced & tasty meal"

- GOAL: **Increased Patient satisfaction**
- GOAL: **Improved patient nutrition**
- GOAL: **Reduced waste**
- GOAL: **Cost Efficiencies**

2. MEASURE AND ANALYSE PROBLEM

Initial Brainstorming

23% of meals wasted due to meals delivered without assistance pre-arranged



Reasons why meals are wasted on wards

Root Cause Analysis

Unstructured communications identified as root cause for meals being wasted

3. IMPLEMENT IMPROVEMENTS

COMMUNICATIONS

Nursing **identify patients requiring assistance** following consultation with AHP and Medical Team which is then **communicated** to Pantry staff who complete menu cards

ASSISTANCE STICKERS

Assistance Stickers are placed on menu cards for patients needing assistance to indicate that Catering should place meal on **green** tray

COLOURED TRAYS

Visual indicator to signify **assistance with eating required**. Meals for patients who require assistance with eating will be served on **green** trays, as opposed to grey trays for all other patients

ASSISTANCE ROTA

Ward staff coordinate **assistance rota depending on number of patients requiring assistance**

MEAL REGENERATION

Regeneration of meals on Green Trays is **planned and scheduled based on ward activity** to allow for time for assisted feeding.

LOOKING FORWARD

Project adopted on St Brigid's ward as part of ward practice

Roll-out has taken place to 3 additional wards

Roll- out plans in place for remaining wards in MMUH

SAVINGS

Reduced food wasted and assistance given to those unable to feed themselves

0% of meals wasted due to meals delivered without assistance pre-arranged

BENEFITS

- Associated **improvement to patient nutrition, recovery and wellbeing**
- **Reduction in waste of nursing and AHP time** inputted in initial patient assessment
- **Improved communication** at ward level
- **Improved co-ordination and teamwork** across disciplines at ward level

SPONSORED BY [redacted]

MATER LEAN PROGRAMME

Hip Hop to Theatre
Acute Hip Fracture Care in the Older Person

Dr Ronan O'Toole, Registrar, Medicine for the Older Person, Eithne Mullen, Advanced Nurse Practitioner, Emergency Department,
Ms Caitriona Murphy, Advanced Practice Physiotherapist, MSK Triage, Ms Karrie Hogan, Cancer Database Project Manager, Cancer Services,
Mater Misericordiae University Hospital (MMUH), Dublin 7.

Mater Lean Academy
Lean Six Sigma for Healthcare

1 Define and Measure the Problem

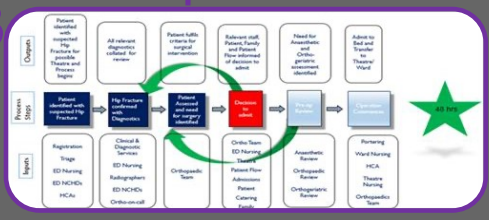
Problem Statement: The [illegible] relative to International best

Increase the % of patients operated within 48 hours	National 70%	MMUH 55%	IHFD 2014
Increase the % of patients receiving a nerve block	National 19%	MMUH 8%	IHFD 2014

2 Analyse

- Delayed requesting of bed
- Two different KPIs leading to confusion re performance
- Limited Orthogeriatric Service Awareness
- Currently no Orthopaedic Trauma Theatre

3 Improve



Improvements Cost Neutral

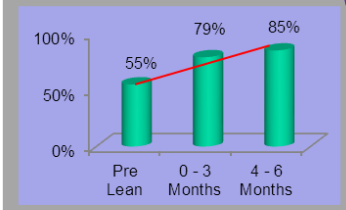
- ✓ Bed requested as soon as fracture identified
- ✓ Optimal Analgesia: Staff training re femoral nerve block
- ✓ Earlier Orthogeriatric input facilitating medical optimisation for surgery

4 Control

- ✓ Earlier bed requesting by ED CNM2 via Fast Track Protocol
- ✓ Formal Incorporation of Orthogeriatric referral into Hip fracture pathway
- ✓ On going training for Nerve Blocks
- ✓ Continuous education for Medical, Nursing and HSCPs involved in Hip Fracture Care
- ✓ Prospective rather than retrospective data monitoring

5 RESULTS

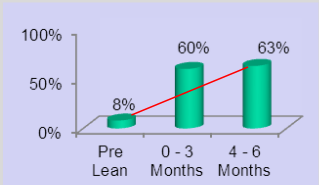
Surgery within 48 Hours of ED Presentation



An increase of **30%** in 6 Months Post Lean

An increase of **55%** in 6 Months Post Lean

Percentage who received Nerve Block



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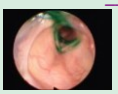
1. Irish Hip Fracture Database National Report 2014 Better Safer Care. www.noca.ie/wp-content/uploads/2015/11/IHFD-National-Report-2014-Online-Version.pdf



SCOPE IT OUT

FEES SCOPE PROCESSING IN MMUH

Ann Marie Darcy, Heather Coetzee, Therese O'Neill,
Mater Misericordiae University Hospital (MMUH), Dublin 7.

1 DEFINE

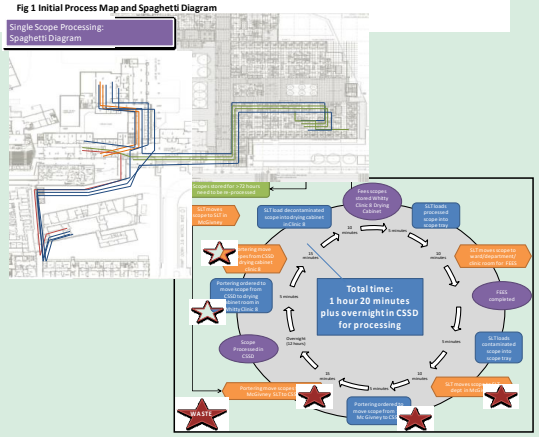
PROBLEM STATEMENT: Speech and Language Therapy (SLT) scopes used for Fibreoptic Endoscopic Examination of Swallowing (FEES) were processed in the Central Sterile Services Department (CSSD) but stored in Outpatient Clinic 8.
There are facilities to process scopes in Clinic 8.

PROJECT GOALS: To map and review current process for SLT FEES scope processing.
Identify waste within current system.
Identify risk within current system.
Propose new process for processing SLT FEES scopes, within best practice guidelines, and eliminate waste, releasing clinical time.
Aim to reduce time for managing the processing of a single scope from 1 hour 20 (plus)minutes, to 35 minutes.

2 MEASURE

Tools used include:
-Process mapping & Spaghetti diagram
Current process resulted in:
-Multiple staff trips between SLT, Clinic 8 and CSSD
-Movement of 'dirty' scopes
-Processes that do not comply with best practice when best practice alternative exists
→1 hour 20 minutes and overnight in CSSD / scope

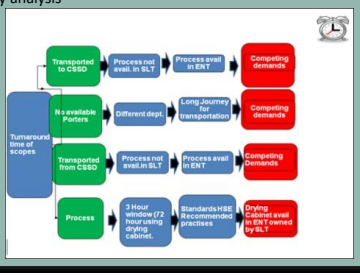
Fig 1 Initial Process Map and Spaghetti Diagram



3 ANALYSE

Group reviewed results of measurement phase and completed:
- Ideal Process Map and Spaghetti Diagram
-Tim Woods
-5 why analysis

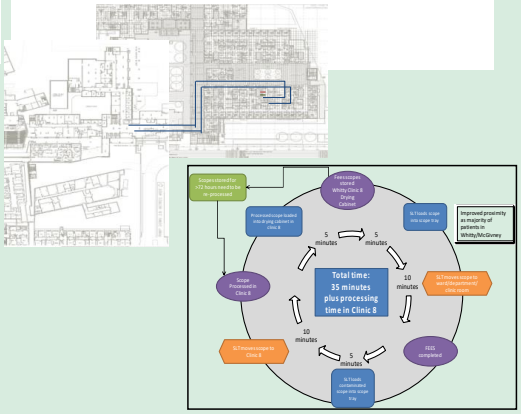
Fig 2 Text



4 IMPLEMENT

Completed practicality scale.
Agreed trial with Health Care Assistants processing FEES scopes in clinic 8.

Fig 2 New Process Map and Spaghetti Diagram



44% time saving
Reduced risk
Best practice

5 CONTROL

Day to day monitoring by SLT and HCAs.
Complete 3 month trial and review.

Mater Lean Academy
Lean Six Sigma for Healthcare

A breath of fresh air

Olivia Lee[1], Roulla Katiri[1], Anna Purcell[1], Alan Wafer[1], & Yvonne Sheppard[2]
[1] Mater Misericordiae University Hospital (MMUH), [2] St James' Hospital

1. DEFINE

The HSE Acute Asthma Management Guideline (NCAP, 2014) has specific recommendations for the discharge and follow-up planning for patients being discharged following an acute exacerbation of asthma[1]. The National Review of Asthma Deaths (NRAD) Confidential Enquiry Report concluded that death could have been avoided in 46% of cases if professional asthma guidelines were implemented[2].

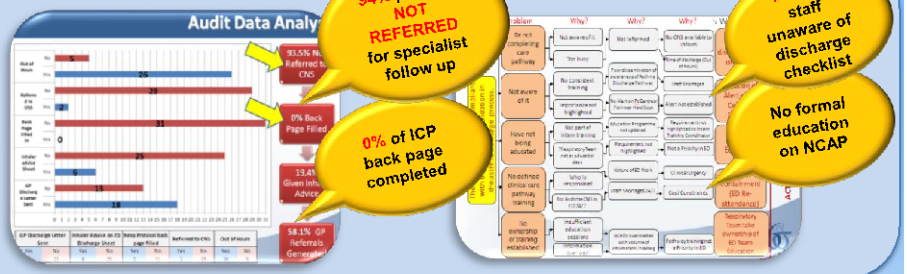
The MMUH Emergency Department (ED) is poorly compliant with the recommendations.

★ **GOALS & OBJECTIVES:** *Increase the number of patients discharged from MMUH ED following an asthma exacerbation with an adequate discharge plan from 0% to at least 30% by 1st of July 2016.*

2. MEASURE & ANALYSE

Data collected:

- Patient Notes Audit
- Staff Online Survey & Interview
- Gemba Walks in ED



3. IMPROVE

4. CONTROL

Education session had an immediate impact:

- ✓ 9% INCREASE in ICP back page completed
- ✓ 20% INCREASE in patients referred for specialist follow up
- ✓ 7% INCREASE in number of patients receiving Asthma Action plan

5. BENEFITS

References: 1. http://hse.ie/asthmaprogramme/. 2. RCP (2014). Why Asthma Still Kills: National Review of Asthma Deaths (NRAD) Confidential Enquiry Report. London: HQIP.

" The Perfect Hour"

Assess the impact of availability of a Senior Clinical Decision Maker on seeing the patient within 60 minutes of presentation to the Emergency Department on PET

Ms. Pauline McGrath Chief Operating Officer
Mr. Keith Carroll ADOM ED/ Patient Flow
Ms. Josephine Ryan Ops Manager ED
Mr. Mark Jeffrey Ops Manager Surgery

Step 1 : Define the Problem

The current model of delivering unscheduled acute care at the Mater Misericordiae University Hospital (MMUH) consists of the Emergency Department (ED), the Acute Medical Assessment Unit and the Acute Surgical Assessment Unit. In practice this can be fragmented and is currently not meeting National Patient Experience Times (PET) . PET is the time measured from registration in ED to departure or admission time.

National Targets

- 95% of all new ED patients to wait less than 6 hours
- 100% of all new ED patients to wait less than 9 hours
- No patient should be in ED > 24 hours

Current State in MMUH

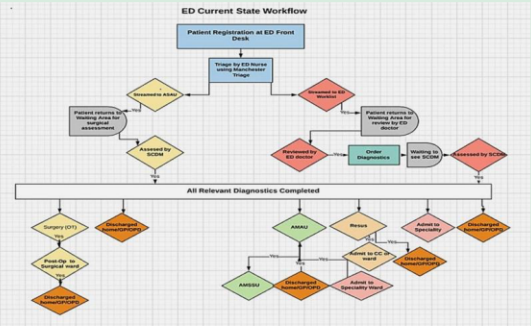
- 58-60% > 6 hours
- 75% > 9 hours
- 6.0% > 24 hours

Average PET for admitted patients of 14 – 16 hours

100% of all patients will be assessed by a Senior Clinical Decision maker within 60 minute of registration in ED.

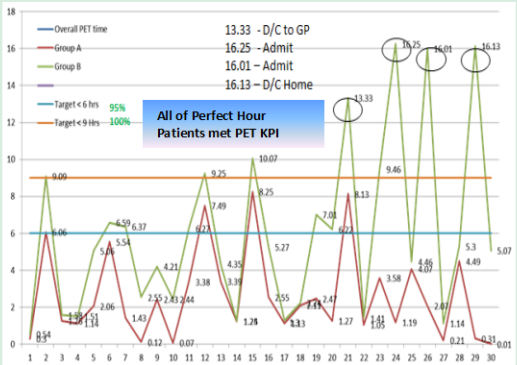
Step 2 : Measure the Problem

Evaluation of the current state processes by process mapping (see below) and key stakeholder focus groups to identify problems and recurring themes.



Step 3 : Analyse

PET – Reg. to DTA or D/C Group A (Perfect Hr. Grp.) vs Group B (Control Current State) – See below for Results

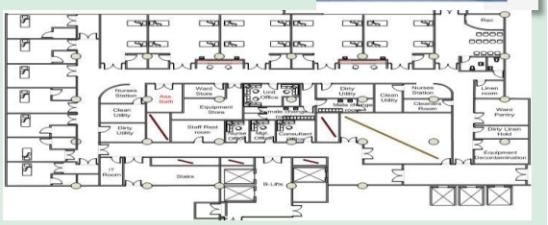


Step 4 : Improve

- ✓ Agree the Acute Floor Model for Implementation with Stakeholders- WIP
- ✓ Approval and sign-off from Acute Floor / Specialty
- ✓ Cohorting Steering Committee - Approved
- ✓ Approval from Executive Management Committee and Board of Directors - Approved
- ✓ Implementation – Working Group for Acute Floor - Established
- ✓ Short Term – Phased Approach to The Perfect Hour – involve Medical / Surgical teams- direct TOC -WIP
- ✓ Results from 'The Perfect Hour' –informed the Business Case
- ✓ Business Case - Completed
- ✓ MMUH – Pilot of Level 4 Hospital for Acute Floor Model - HSE
- ✓ Approval of funding for development of an Acute Floor adjacent to ED - WIP
- ✓ Organisational Stakeholder Communication Plan – WIP
- ✓ RIE for Floor to Ward September 2018
- ✓ Discharge Lounge – October 2018
- ✓ Home by 11.00 Initiative - WIP
- ✓ Medical Registrar at point of registration – Winter Plan 18/19

Step 5 : Control

1. **Business Case Complete submitted as part of Estimates Process for 2019**
2. **First Draft of Acute Floor Plan has been submitted to HSE for Funding**



REFERENCES: **1.** NSW July 2012 Government Emergency Departments Models of Care **2.** Israe S., Digiust E., Sonntag P., Dann L., Fox D., (2008) Streaming by case complexity: Evaluation of a model for emergency department Fast Track. Emergency Medicine Australia. **3.** HSE, Developing an Acute Floor Model for Ireland, Version 1.0 October 2017 . **4.** Lowthian J., Curtis A., Straney L., McKimm A., Keogh M., Stripp A. (2015). Redesigning emergency patient flow with timely quality care at the Alfred. Emergency Medicine Australasia.

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Project Group: Michele McCormack • Peter Spencer • Kieran McDonnell • Karen Sheehan
"How are we doing" board
58 minutes POST COW implementation
Discharge Paperwork to be completed
Computer on Wheels Mother with WI-FI to speed up test ordering / test results

'DRUGS ROUND'

Improving Efficiency of the 8am Oral Medication Round

WARDS 2

Project Group: Mary Cleary, Marissa Kieran (Replaced by Maria Creed at Implementation Stage)
Aileen Igoe

1. DEFINE & MEASURE PROBLEM

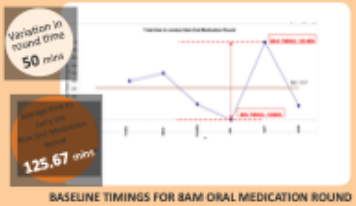
PROBLEM STATEMENT: *'Provision of nursing care is increasingly more challenging with more complex patient profiles, more acute patient needs and reduced resources. Current practices are resulting in a nurse spending on average 20% of their day carrying out Oral Medication Drugs Rounds.'*

GOALS

- GOAL — **Eliminate** any non-necessary steps
- GOAL — **Reduce** interruptions
- GOAL — **Improve time** lost by 20%
- GOAL — Provide a **safer environment** for drug administration

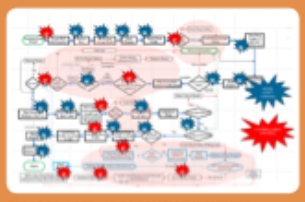
On average, a nurse dispenses **14** drugs to a patient in **1** day

Increased disruption = increased risk in medical related errors

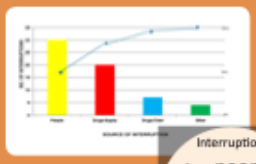


BASELINE TIMINGS FOR 8AM ORAL MEDICATION ROUND

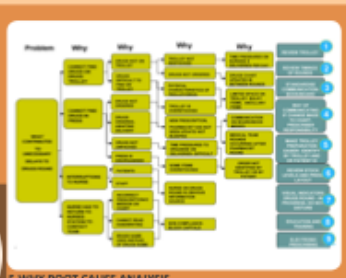
2. ANALYSE PROBLEM



AREAS OF WASTE AND VARIATION IDENTIFIED THROUGH PROCESS MAP



Interruption from **people** and **drugs** **supply** tallied as root causes of delays



5 WHY ROOT CAUSE ANALYSIS

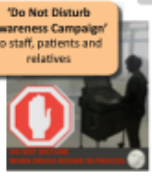
3. IMPLEMENT IMPROVEMENTS

Reorganisation of Drugs Trolley layout

Use of Andons (visual indicators) to **identify stocking requirements** and issues with Drugs Chart

Standard process and checklist for carrying out Drugs Round

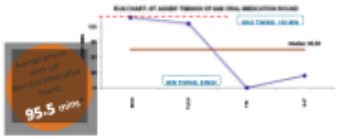
'Do Not Disturb Awareness Campaign' to staff, patients and relatives



Regular Auditing and clearing of Drugs Trolley

Visual Management 'Do Not Disturb signage' on trolley and ward

Standardised Communication Board between pharmacy and nursing



'Before the project, everyone had a different way of carrying out the round. Now everyone knows which trolley the drugs are for and knows that they will be put away - the pilot helped structure and standardise.'
Mary Cleary CNM2 St.Agnes' Ward

'The checklist and andons will be very helpful for agency staff and students'
Staff Nurse on St. Agnes' Ward

'I found the whiteboard very useful as the area requesting the drug was highlighted e.g. T1/T2'
Pharmacist on St. Agnes' Ward

BENEFITS

- Increased **efficiencies on ward** with potential to release time for direct patient care
- Increased **concentrated time** to carry out the drugs round and reduced risk of medication error
- **Reduced frustration to nursing staff** carrying out the round - **reduced searching** for drugs in trolley, **reduced return journeys** to the drugs supply room
- **Increased communication** and teamwork across disciplines
- **Improved communication** for a smoother patient journey

SAVINGS

8am DRUGS ROUND ST AGNES' WARD (SURGICAL) **30.1 mins** SAVED PER ROUND

8am DRUGS ROUND ST VINCENT'S WARD (MEDICAL) **30.46 mins** SAVED PER ROUND

VARIATION REDUCED FROM **50 mins** TO **23 mins** on St. Agnes' Ward

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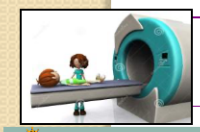
MATER LEAN PROGRAMME



ZAP IT, TRACK IT

Kathleen McGrath (MMUH), Maircad Casserly (MMUH) and Freda O'Mara (IEHG)

1. DEFINE

National Peritoneal Malignancy Institute

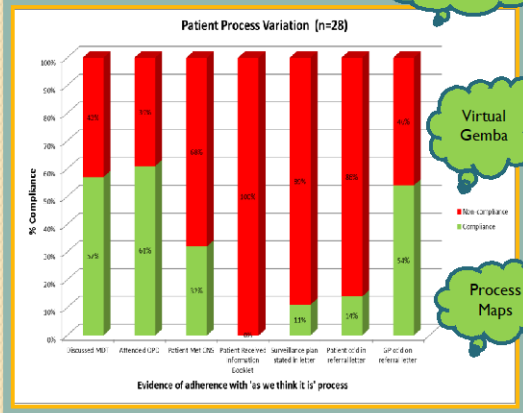
- The National Peritoneal Malignancy Institute was set up in MMUH in 2013 to treat patients with peritoneal surface malignancy, including LAMN.
- 23% of patients diagnosed with LAMN are at risk of developing Pseudomyxoma Peritonei (PMP) without appropriate surveillance, to include annual CT Tap & bloods [1].
- If left untreated, the median survival time for peritoneal cancer patients may be as short as six weeks to six months [2]. Cyto-reductive surgery & HIPEC is the optimal approach for PMP.
- There is significant morbidity and a cost of approximately **€40,000** associated with HIPEC.
- Of the 28 MMUH LAMN patient's under surveillance, **39% have not had an annual CT.**

2. MEASURE

Stakeholder engagement

Virtual Gemba

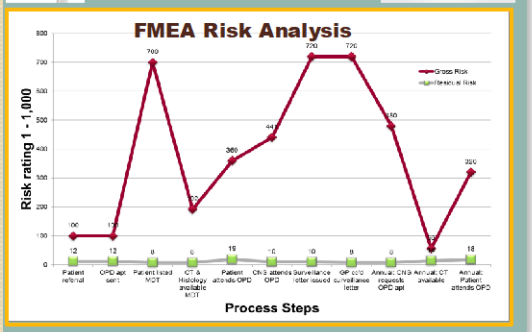
Process Maps



Results of Phone Survey

- I was not introduced to the CNS and had to get her number through switch
- CNS got in contact very quickly when I left a message
- I didn't know the Mater had a service for this
- Not sure who organises my CT, the Mater or my GP?
- I would love to know more about PMP!
- I had to google PMP!

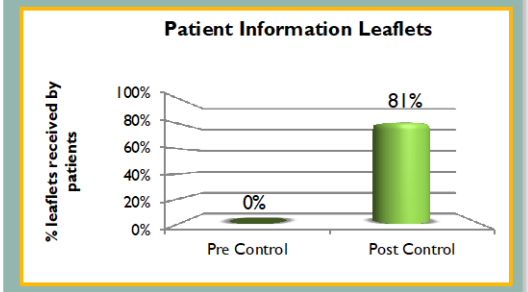
3. ANALYSE



4. IMPLEMENT

Item	Project Improvement	Implementation Date	Process Step	November 2017– Green/Amber/Red
1	Eliminate current excel database (duplication of process).	November 2017	CNS/Data Manager tracks patients for surveillance.	Implemented
2	Retrospectively sent out information leaflet and contact details to current patients.	November 2017	Patient informed of surveillance plan.	Implemented
3	IT to facilitate computerised generation and verification of information leaflet and contact details on Patient Centre.	November 2017	Tracking/Auditing of patient receiving the information on their treatment plan	Implemented
4	IT to facilitate computerised generation and verification of a standardised surveillance letter on Patient Centre.	December 2017	Patient informed of surveillance plan. Referring Hospital informed of surveillance plan. GP informed of surveillance plan.	Implemented
5	Creation of SOP pathway for LAMN patients.	December 2017	Referral of patients: OPD, MDT and CNS.	In progress
6	Add new fields to current Peritoneal Registry Database (PATS) in order to capture follow up of LAMN patients.	January 2018	Recording of follow up surveillance for LAMN patients.	Implemented
7	Data Manager to Flag monthly with CNS potential LAMN patients for follow up by pulling patients from the PATS system.	January 2018	Annual Surveillance Follow up.	Implemented
8	Arrange slot to present Project's data and referral at the Colorectal Team Meeting every 3 months	January 2018	Referral of patients: OPD, MDT and CNS.	Implemented

5. CONTROL



Annual Surveillance Improvement from 61% to 77% (as of 19th February 2018)*

** based on 35 patients surveillance to date*

REFERENCES:

1. Foster JM, Sleightholm RL, Wahlmeier S, Loggie B, Sharma P, Patel A. (2016) "Early identification of DPAM in at-risk low-grade appendiceal mucinous neoplasm patients: a new approach to surveillance for peritoneal metastasis." World J Surg Oncol. Sep 13;14(1):243.

2. http://www.hipec.com/peritoneal-cancer/ accessed 27/06/17

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'OPD DNA'

Improving Out Patient Attendance Rates

OPD 3

Project Group: Olivia Merrigan, Therese O'Neill, Claire Sheridan

1. DEFINE PROBLEM

PROBLEM STATEMENT: *'In 2012, DNA rates in OPD Clinics in the Mater ranged from 3% to 27%, with an average of 20.86% across all OPD Clinics. These high rates are leading to prolonged waiting lists, overbooking of clinics, overtime costs, patient frustration and staff stress.'*

16,632 DNAs in 2012

Wasted clinical and administrative time in setting up appointment, preparation for clinic and rescheduling of appointment

€53.15 per DNA

Wasted man-hours (prep etc)

€883,991

GOALS & OBJECTIVES

GOAL — This project aims to construct and implement **improved procedures** to reduce the overall DNA rate in the Outpatients department of the Mater Hospital

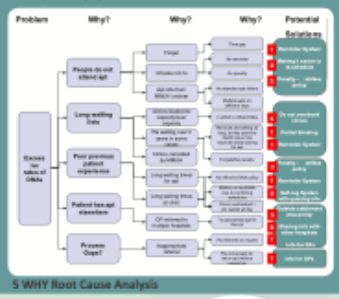
GOAL — To create systems and procedures to ensure the **optimal allocation of clinic slots** and reduce the overall waiting times for OPD clinics

2. MEASURE & ANALYSE PROBLEM

WHY DO PEOPLE DNA?*

- PATIENT UNAWARE OF APPOINTMENT — 8%
- PATIENT FORGOT — 12%
- APPOINTMENT NO LONGER NEEDED — 8.5%
- OTHER — 16.7%
- NO ANSWER / WRONG NUMBER ON PATIENT CENTRE — 29.8%
- NO REASON GIVEN — 17%
- PATIENT TRIED TO RESCHEDULE — 8%

*Results from phone survey of patients who DNA'd

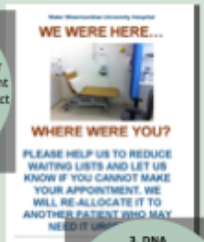


5 WHY Root Cause Analysis

3. IMPLEMENT IMPROVEMENTS

1. DNA POLICY Incorporation of SDU policy proposals into MMUH policy + processes + approval of same

2. TEXT REMINDER SYSTEM introduced by another MMUH improvement project



8. PATIENT OUTCOME SHEET Ensure appointments are booked according to Consultant instructions

3. DNA AWARENESS CAMPAIGN Poster campaign in clinics, DNA info on Appointment Letter, DNA info on website

6. GP AWARENESS CAMPAIGN Utilise HEALTHLINK+ MMUH

4. EASY RESCHEDULING OF APPOINTMENT Contact directed to Clinic Secretary to aid easy rescheduling

7. GP TRAINING DAYS Raise awareness of DNA impacts and improve compliance with MMUH DNA policy

5. WEB & DOCUMENTATION ALIGNMENT Clear information on new DNA policy

LOOKING FORWARD

POLICY APPROVED SEPTEMBER 2013

OCTOBER 2013 Policy refinements by SDU- **1 strike policy**

OCTOBER 2013- DECEMBER 2013 Full Implementation of DNA Awareness Campaign – changes to website, letters, appointment cards, GP Info

DECEMBER 2013 Remeasure baseline data

SAVINGS & BENEFITS

REDUCTION IN DNA'S WILL ALLOW

- SCHEDULING OF DEDICATED EMERGENCY SLOTS
- REDUCED WAITING LISTS
- NO OVERBOOKING OF CLINICS

New OPD DNA Policy implemented **1 strike policy**

Initial pilot results show improvement in DNA Rates

Initial data showing downward trend in DNAs from Text Reminders

SPONSORED BY

MATER LEAN PROGRAMME

Streamlining the referral process and increasing the referral rate to Pulmonary Rehab after an admission for an exacerbation of COPD

'Save your Breath'

Vanessa Kelly, Chief Operations Office
Rosemarie Geary, Blood Transfusion Lab
Jennifer Stafford, Physiotherapy Dept.
Michael Rowan, Medical Physics

Step 1: Define the Problem

- Chronic Obstructive Pulmonary Disease (COPD) is the 3rd highest cause of respiratory death in Ireland with exacerbations tending to result in hospitalisation with high health care costs.
- Best practice recommends referral to Pulmonary Rehabilitation (PR) within 2 weeks of an acute exacerbation.
- Anecdotal evidence suggests that there is large variability in the referral process and suboptimal referral rates to PR on discharge from MMUH.

So what are our project objectives?

1. Increase awareness of PR
2. Streamline the referral process
3. Increase the referral rate

Step 2: Measure the Problem

1 Calculate the current referral rate to PR

$$\text{Referral Rate (\%)} = \frac{\text{Referrals made (electronically + by paper)}}{\text{No. of Patients discharged after COPD exacerbation}}$$

2. Establish the awareness of key stakeholders on the PR referral process & pathway

SurveyMonkey

Online survey

3. Establish the reasons why the referral rate is so low

Focus Groups with the 3 key referrer groups

Step 3: Analyse the Problem

1. Referral Rate (n=224)

- Received a Referral
- Did not receive a Referral

37%

2. Awareness

43% unaware of how to send the referral

18% unaware of PR

referral is satisfactory

"Patient Education"

"Staff Education"

"No tracking of Referrals"

Step 4: Improve

Staff Education + Patient Education + Review and re-launch referral Form + Standardised referral process + Referral form accessible electronically

Step 5: Control

Awareness

83% of key stakeholders are accessing the standardised referral form electronically and view the process as satisfactory

Streamlining

Electronic Referral

Two fold increase in the monthly no of electronic referral forms generated

SAVE THE DAY

THORACIC ENHANCED RECOVERY PROGRAMME

Mater Hospital Dublin

Mater Lean Academy
Lean Six Sigma for Healthcare

UCD DUBLIN

R Brown, P Grehan, E Moore, A Brady, M Brennan,
D Carter, SP Teeling, KC Redmond, D Eaton

The Mater Misericordiae University Hospital, Dublin, Ireland

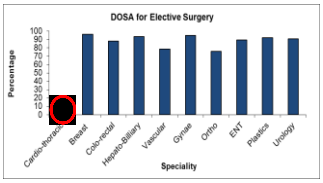
DEFINE

PROBLEM STATEMENT

The Mater Misericordiae University Hospital currently has an increasing length of stay within the Cardiothoracic department (AvLOS 12 days) (HIPE MMUH May 2016). The Enhanced Recovery Programme helps streamline and standardise care delivery to patients and could reduce length of stay by 1 day with access to day of surgery admission (DOSA) beds. Currently mixed CTS data suggests there is only 10.9 % compliance for DOSA in 2015 across 9 surgeons as per HIPE data.

GOALS

- To reduce LOS by 1 day
- To increase DOSA in line with national figures of 75%
- To increase awareness of the Thoracic Enhanced Recovery Programme

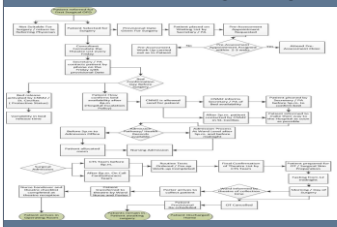


MEASURE & ANALYSE

The process map was completed 3 times to illustrate the change & waste

- Pre- thoracic enhanced recovery pathway until September 2015 (AS IT WAS)
- Since the introduction of the enhanced recovery CNS (AS IT IS)
- The pathway post lean processes and philosophy (AS WE WOULD LIKE IT)
- Voice of the customer was collected from both the staff and patients, questionnaires and patient interviews
- Data from the virtual gemba illustrated a high cost associated with wasted rework
- The fishbone identified areas of change required to reduce waste

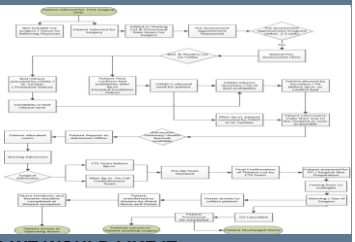
AS IT WAS….



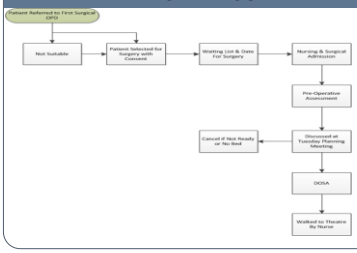
42 potential steps from surgical OPD to theatre

AS IT IS…..

36 potential steps from surgical OPD to theatre



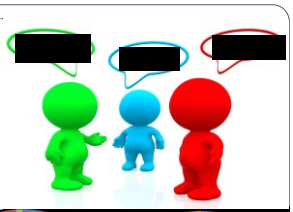
AS WE WOULD LIKE IT…..

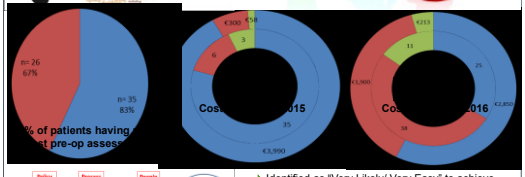


10 potential steps from surgical OPD to theatre

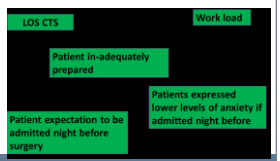
1st PTU bed 19/01/17

1st patient walked to theatre 26/01/17

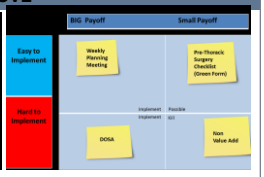


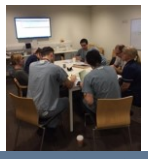


Identified as "Very Likely/ Very Easy" to achieve



IMPROVE





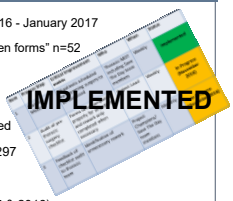
The Improve Phase:

- Development of the thoracic surgical checklist (green form)
- Weekly Tuesday morning planning meeting for the thoracic MDT
- Weekly audit of the green form

CONTROL

The Control phase took place between November 2016 - January 2017

- Weekly audit of the thoracic surgical checklist "green forms" n=52
  - 50 patients had NO rework (96%)
  - 2 patients had blood tests repeated
  - 1 patient had a CXR and Swabs repeated
  - Total cost of rework over 3 months = € 297
  - 63% and 79% reduction in rework when compared to the virtual gemba data (2015 & 2016)
- The introduction of DOSA was planned for January 2017
  - To date 1 DOSA bed has been planned and accessed in the PTU each Thursday over the past 4 weeks



Audit to be continued by Thoracic CNS/ Team

Hip Hip Hooray

Streamlining the Patient Journey from Ward to Theatre

Team Members: Bernadette Mee, Irene Aloveros, Donna Brazel, Peter Krysztofiak
Mater Misericordiae University Hospital, Dublin

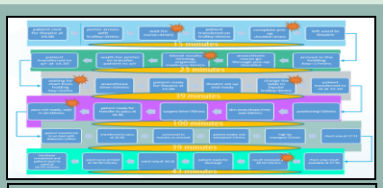
1 DEFINE

PROBLEM STATEMENT: A first generation Lean project 'Hip Hop to Theatre' looked at the patient pathway from the Emergency Department to Theatre. Aiming to streamline the patient pathway in line with the National Hip Fracture guidelines. The project scope ended at the theatre door. This project, Hip Hip Hooray followed the pathway of the hip fracture patient from ward to theatre and back to ward, reviewing the process to eliminate non value add (NVA) for patients and staff alike.

PROJECT GOALS & OBJECTIVES:

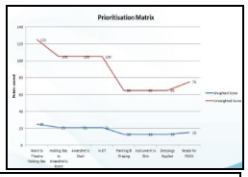
1. Continue to eliminate NVA processes to the patient pathway as a direct continuation of the Hip Hop to theatre project.
2. Reduce length of time from patient requested from ward to start of surgery (from baseline data of 94 minutes).

2 MEASURE



- Internal KPI that 95% of patients will arrive in the Holding Bay within 30 minutes of patient being requested from ward, 60% of the 39 patients met this KPI.
- Average turnaround time of 39 patients from ward to start of surgery was 94 minutes.
- Analysis of patient pathway to eliminate NVA process.

3 ANALYSE



- The TIM WOODS model of analysis identified causes of delay which included, incomplete documentation/diagnostic results, inadequate availability of abduction pillows and porter availability.
- It identified that these steps/processes should be completed pre-operatively, before the patient goes to theatre, and this is reflected in the prioritisation matrix where the highest score was the timing from ward to theatre holding bay.

4 IMPLEMENT

Effective use of TMS
Training and utilisation – on going and extended to wards

Defining and mapping of ward to theatre route
Faster route sought

Availability of abduction pillows
Disposable pillows sourced

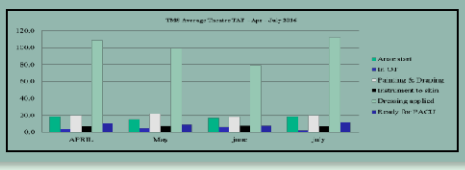
CSSD access on theatre list
Prioritised instruments availability

Briefing and debriefing
Theatre huddle before start of list

- Effective use of TMS system will give information of the progress of the list in Theatre. Preparation of patients, documentation and other equipment/resources required are obtained in a timely manner to avoid delay.
- There is a potential saving on reduction of waiting time or TAT.

5 CONTROL

- ✓ Continuous training on TMS system.
- ✓ Ward informed that this cohort of patients need abduction pillows and have identified storage and availability.
- ✓ Discussion on-going to identify faster ward to theatre route.
- ✓ Theatre huddle at start of list.
- ✓ Communication with CSSD prioritizing instrument availability.
- ✓ Continuous monitoring and reporting of TATs.
- ✓ TMS capturing patient called for, a suggested update.



REFERENCES:
Hip Hop to Theatre (Lean Green Project)
W2P3 Reducing patient turnaround times for theatre (Lean Green Project)
TMS (Theatre Management System)
Irish Hip Database

Mater Lean Academy
Lean Six Sigma for Healthcare

SUITE SCOPING

Dr. Brian McCullagh, Erin Daly, Meave Corcoran, Fidelma Mac Hale
Mater Misericordiae University Hospital (MMUH), Dublin 7.

Mater Lean Academy
Lean Six Sigma for Healthcare

1 DEFINE

Problem Statement

State of the art bronchoscopy suite with under-utilisation of capacity (15%) and a perception that the unit was not operating efficiently.

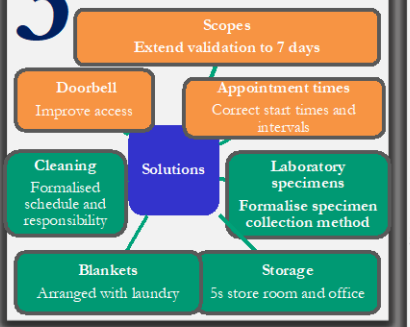
Aims

Efficiency	• Start on time increase by 90% • 90% of TAT to be within one hour
Patient Experience	• 100% satisfaction
Quality	• Hygiene audit 100%
Resource Utilisation	• 5S audit 100% • Enhance services provided

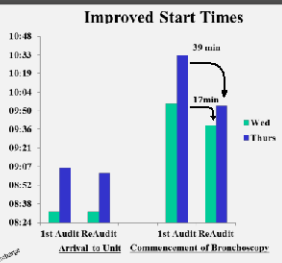
2 MEASURE

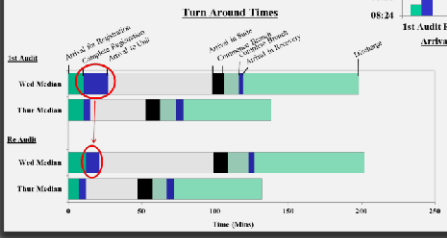
Aims	Measure	Comments/findings
Efficiency	Turn Around Times Start and Finish Times	Variations in list management on alternate days Delayed start and finishes
Patient Experience	Satisfaction Surveys	Very high satisfaction rate
Quality	Review of RMOF and of hygiene audits	Few low risk RMOF 33% hygiene audit compliance
Resource utilisation	Utilisation Rates Availability of resources (staff & equipment)	Significant available capacity Timely availability of clean scopes

3 IMPROVE



4 RESULTS





5 CONTROL

Efficiency

CGM ENDORAAD
Integrated Endoscopy Clinical Information System

EndoRaad to monitor monthly start and finish times and TAT's

Patient Experience

Annual patient satisfaction surveys

Quality

HYGIENE AUDIT
33% ➡ 100%

Monthly results to be displayed publically

Resource utilisation

Opening 2nd room for pleural based procedures

Recommendation - Irish Thoracic Society to adapt /adopt the British Thoracic Society 'Quality Standards for Flexible Bronchoscopy (2014)' as National standards

Going Viral

Reducing Rejection of Virology Specimens

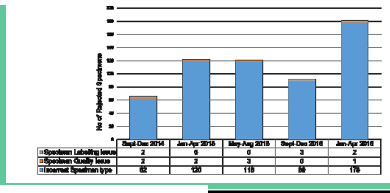
Jackie Cafferkey, Karen Fitzpatrick, Sinead Buckley, Noel Gallagher, Cian Fitzpatrick, James Connell
Mater Misericordiae University Hospital (MMUH), Dublin 7

DEFINE

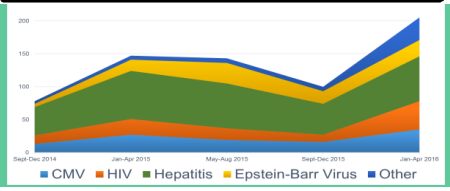
The microbiology laboratory in the Mater Misericordiae University Hospital has a KPI for specimen rejection of <2% for all specimen types. The current rate of rejection for virology specimens, referred to the National Virus Reference Laboratory (NVRL), is approximately 4%; >90% of rejection is due to incorrect blood tube/specimen type selection during patient sampling. Specimen rejection in virology specimens results in a delay in viral infection diagnosis/exclusion, increased patient trauma due to re-collection, higher risk of test abandonment, and non-value added use of laboratory resources.

MEASURE

Reasons for Specimen Rejection Sept 2014-Apr 2016

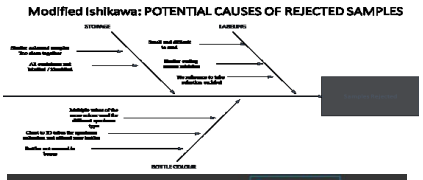


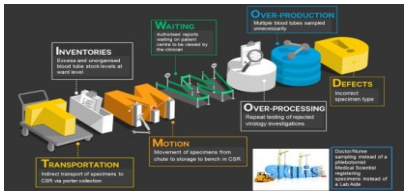
Breakdown of Rejected Samples by Investigation Type Sept 2014-Apr 2016



ANALYSE

Modified Ishikawa: POTENTIAL CAUSES OF REJECTED SAMPLES





IMPLEMENT

With the use of a PICK chart we selected solutions that were feasible and effective.

- To develop a virology quick reference guide.
- Establish advisory messages on targeted virology orders on patient center.
- To perform 5s on Pilot ward blood bottle storage.
- Confirm inclusion of specimen type on soon to be introduced MedLis Barcode labels.

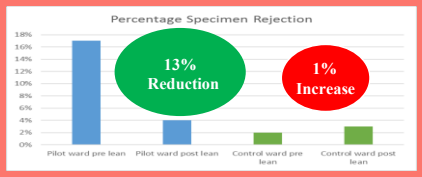
From

Full Baskets

To

Clearly labelled cubby holes

CONTROL



- Reduction in rework and patient anxiety.
- Reduced repeat venepuncture for patients
- Positive effect on bed management.
- Timely & accurate diagnosis leading to appropriate medical interventions for patients

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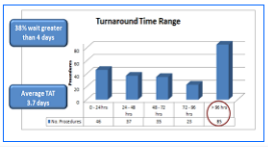
PICC 'n' Go!
Improving Waiting Times for PICC Line Procedures

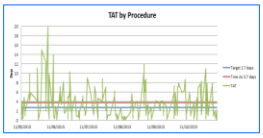
Ann Dolan, Danny Dunne, Ann Hannon, Carl Hubbard

1. DEFINE PROBLEM

PROBLEM STATEMENT: *IR procedures vary from major to minor interventional complexity. IP PICC Line procedures are 23% of total referrals. Average IP TAT is 3.7 days but 38% wait greater than 4 days adding to IP ALOS*



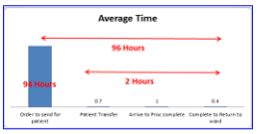
PROJECT GOALS:
1. *Reduce* TAT to 2.7 days
2. *90%* of IP seen within 3 days



Voice of Customer
- *"..increased length of stay.."*
- *"..chemo and treatment delay.."*
- *"..patient anxiety increased.."*

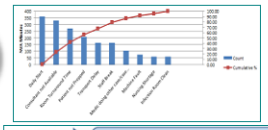
2. MEASURE & ANALYSE

Virtual and Live Gemba



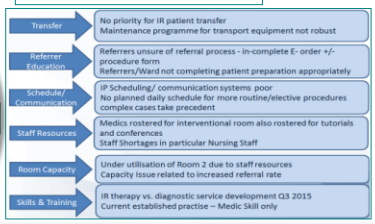
Up to 96 hour wait for 2 hour activity:

Room Usage



= Delayed morning start

"5 WHYs"
1. Process
2. Room utilisation



3. IMPROVE Q2-3 2016

1. Referrer Education

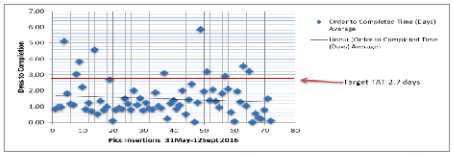
On-line procedure form

Ward Checklist

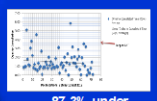
2. Schedule /Ward Communication

- Dedicated Porter 8-10am.
- Admin sends for patient at 8am.
- Communicate with wards evening before
- Schedule Patient x 2 next morning
- Paper work & bloods complete

3. Implement – THE RESULTS



Consistent Service: Variation Reduced



87.3% under 3 days

Implement phase June to 12 Sept 2016:

106.76 ÷ 72 = 1.48 day Turn Around Time

2016 YTD: 354.52 Divided by 158 days = 2.24 TAT

VOICE OF CUSTOMER

Admin Manager: "It's (2x PICCs) become embedded in the day"

CNM2: "Comms with IR & TAT improved!"

4. CONTROL Q3/Q4 2016/2017

Maintain Process Improvement

Room Capacity Q3 2016	*Focused List Room 2 – Reallocation of Staff*
Skills & Training Q4 2016 / Q1/2 2017	*Skill Mix– PICC Insertion Training Radiographers/Nurses*

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Screen Saver
A project to improve pre-op screening in cardiac surgery

Project Group: Patrick Stapleton, Maria Lenehan, Liz Whitney, Olive Flynn

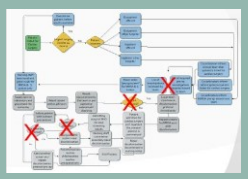
1 Define the problem

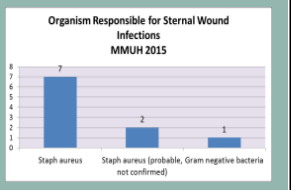
Patients undergoing major cardiac surgery are at risk of Surgical Site Infection (SSI), most often caused by the bug Staph aureus or "Staph". An effective pre-operative screening programme can decrease SSI rates. We screen for Staph carriage with a simple nose swab, then give an eradication nasal ointment to carriers. If the screen result is not ready in time for surgery, we can give eradication treatment to all patients, but this has a risk of causing antibiotic resistance and is not ideal. In MMUH swabs are taken on eve of surgery.

A baseline Audit of pre-op screening revealed that **0%** of results were available prior to surgery: target for improvement is **50%**

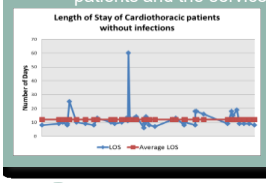
2 Measure

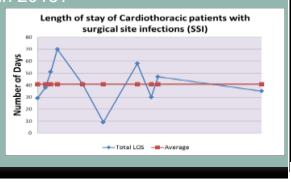
"As is" process flow map was developed, it shows pre op screen are not requested early enough, Non value added steps are highlighted in red.





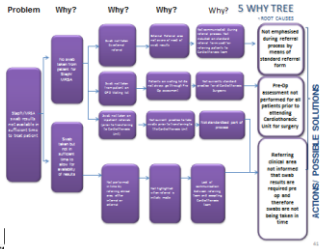
What was the effect of these infections on the patients and the service in 2015?

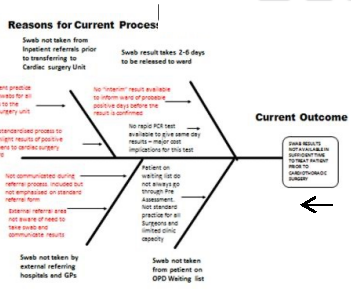




3 Analyse

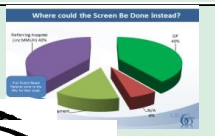
What are the root causes of the lack of timely availability of swab results?

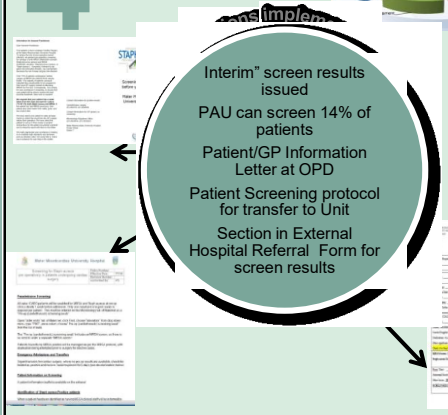




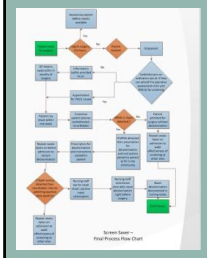
Root causes explored with priorities for cost effective change highlighted in red

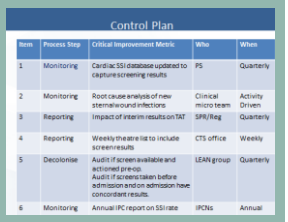
4 Improve



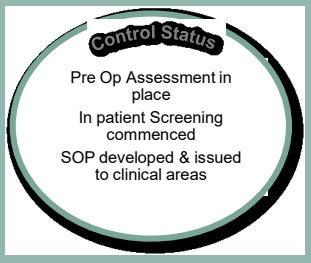


5 Control





Item	Process Step	Critical Improvement Metric	Who	When
1	Monitoring	Cardiac SSI database updated to capture screening results	PS	Quarterly
2	Monitoring	Root cause analysis of new sternal wound infections	Clinical micro team	Activity Driven
3	Reporting	Impact of interim results on TAT	SPR/Reg	Quarterly
4	Reporting	Weekly the atre list to include screen results	CTS office	Weekly
5	Decolonise	Audit if screen available and actioned pre-op. Audit if screens taken before admission and on admission have concordant results.	LEAN group	Quarterly
6	Monitoring	Annual IPC report on SSI rate	IPCNs	Annual



Lean Genes: Staying on Track

Improving tracking of Lynch Syndrome tissue testing requests and results in the Cancer Genetics Service of the Mater Misericordiae University Hospital

Claire Giffney, Berna Guest, Rita Marron, Davina Shaw, Professor David Gallagher (Project Champion)
Mater Misericordiae University Hospital (MMUH)

DEFINE

At present, there is no quality, systematic, live, centralised method of logging evidence of requests for tumour sample testing for Lynch Syndrome, and tracking the progress of the request and result within the Cancer Genetics Service (CGS) of MMUH.

The lack of a robust method for identifying failures/weaknesses within the current requesting and tracking process may result in a patient who is at risk of Lynch Syndrome not receiving the most optimum assessment.

Manual logging & tracking of requests by CGS team in Excel

Risk of delay or absence of results for patients

Delayed or incomplete assessment for patient:
- Cancer risk
- Optimal surveillance
- Genetic testing

MEASURE

Virtual GEMBA

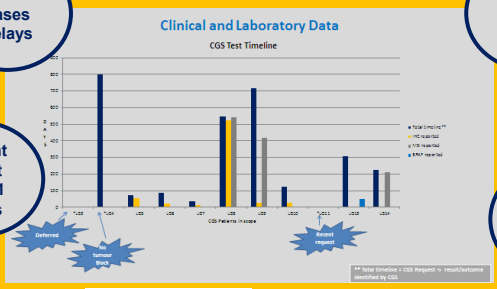
High level process maps

Retrospective Audit of charts & EPR

Stakeholder Interviews

5/11 cases delays

Absent result in 1/11 cases



Rework required in 45% of cases

Estimated Annual Cost to CGS to track status/ outcome: €4,300

Case timelines Range: 54 -799 days

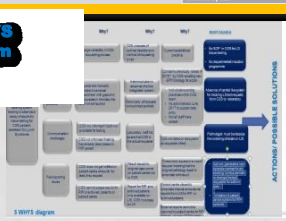
ANALYSE

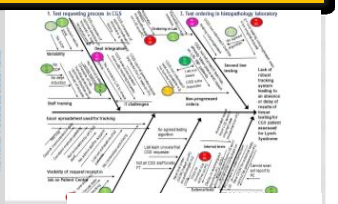
0% of original requests sent directly to laboratory Historec email address

CGS listed as requester on LIS/Patient Centre in 0% of cases

0% of reports notified to CGS team on Patient Centre

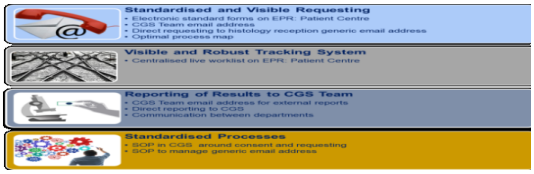
5 WHYS Diagram

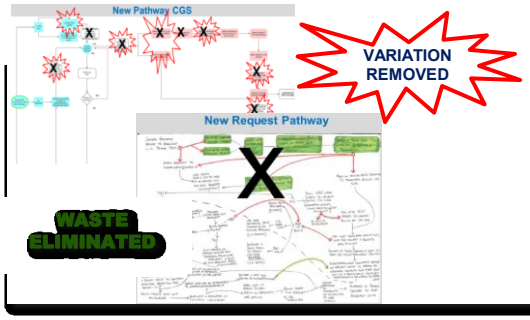




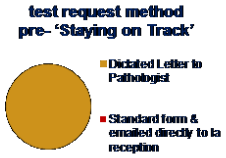
Ishikawa Diagram

IMPROVE





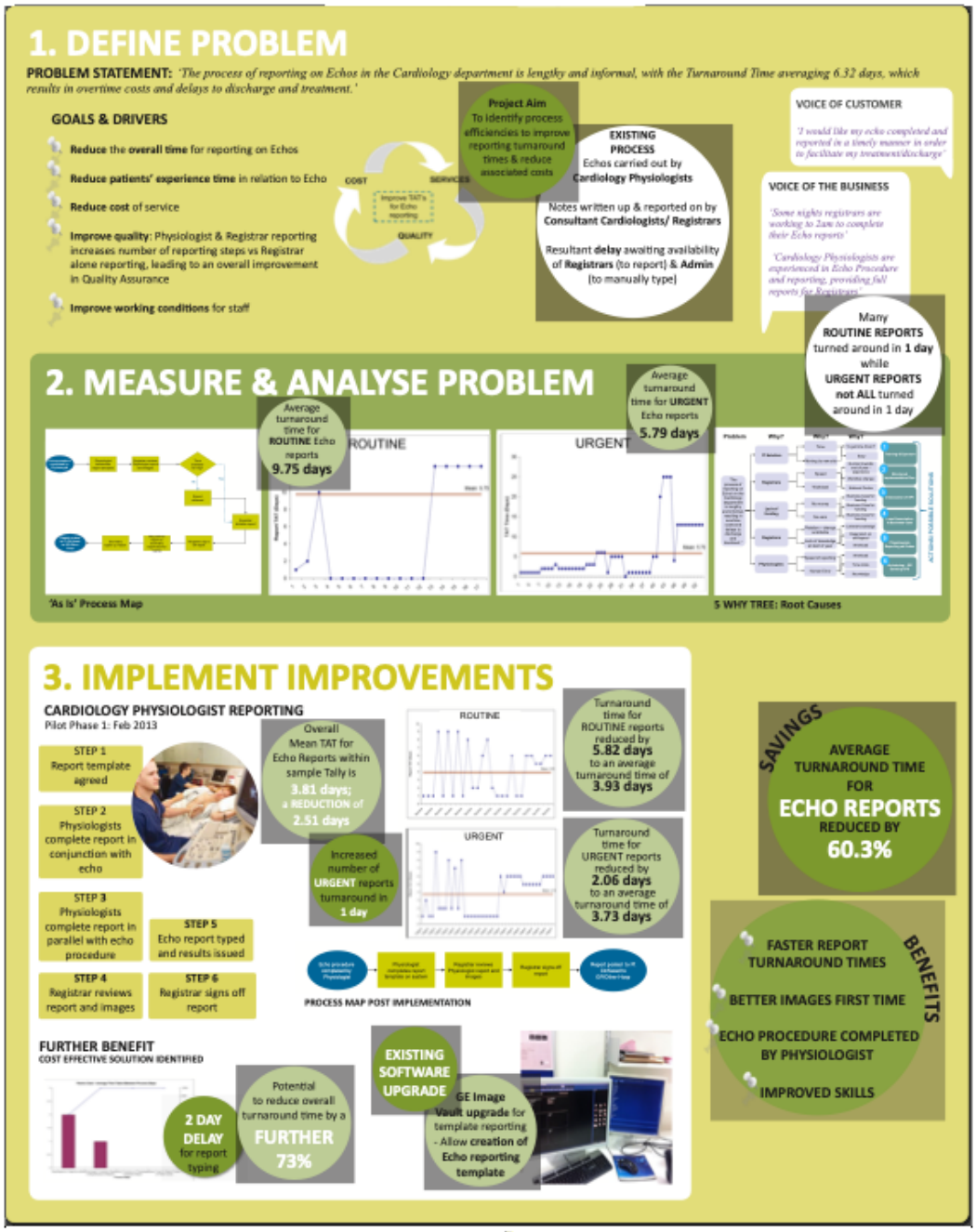
CONTROL



	Pre- 'Staying on Track'	Post' Staying on Track'
Visibility and traceability of requests from CGS on patient centre (%)	0%	100%
Case timeline range (days)	54-799	31-33

'ECHO REPORTING PROJECT'
Reducing Turnaround Times on Echo Reports

Project Group: Robbie Ryan, David Lynch, John Keaney



SPONSORED BY

MATER LEAN PROGRAMME

REMOTE MONITORING

Paul Ryan, Jack O'Shea, Iain Lawrie, Caoimhe Fitzsimons (MMUH) Catriona McGrath (SLHD)

D

5-fold growth

M

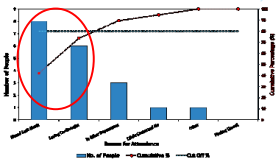
Voice of Customers: Patient Focus Group

- I am really happy with the current service.
- I like the personal touch but a phone call would be fine.
- I found the DVD explaining RM was a great help.
- A trial run might help.

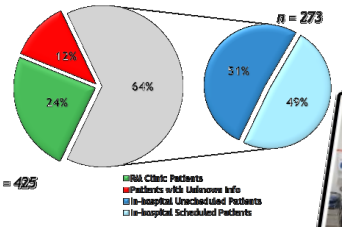
Cardiac Physiologists' Focus Group

- Need more time to explain.
- Education is key you can't give the patient enough information
- Patients just pop in.
- Patients do not realise the importance of the device.

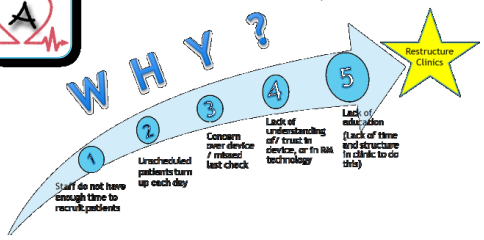
Cardiac Physiologist, Patient, RM Clinic Gemba's



Clinic Attendance Data (April 2016)

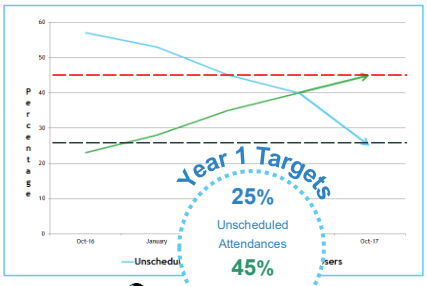


A

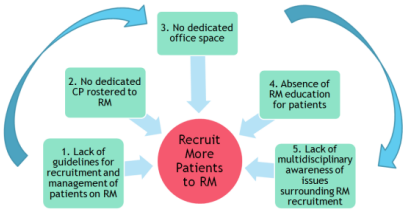


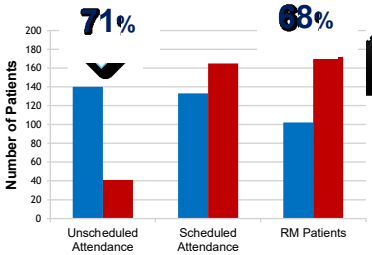
I

C



Potential Vital X's Ranked





Mater Lean Academy
Lean Six Sigma for Healthcare

Appendix 4.2 : Application document Checklist

Research Study title: *The contribution of Lean Six Sigma to person-centred cultures in a university hospital*

Declaration of the Mater Misericordiae University Hospital or Mater Private Hospital Principal Investigator

- **I certify that the information in this application is accurate to the best of my knowledge and I take full responsibility for it** ☑
- **I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in the International Conference on Harmonisation's Good Clinical Practice Guidelines (ICH GCP)** ☑
- **If the research study is approved I undertake to adhere to the research study protocol and to comply with any conditions set out in the letter of approval sent by the Recognised Ethics Committee** ☑
- **I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of patient or other personal data** ☑

Signature:

Print Name: **SEÁN PAUL TEELING**

Date: **31st August 2018**

This declaration must be signed and sent with all documents as per Number 16 of the Application Document Checklist on page 2 of this document otherwise the application will be considered as invalid and will not be reviewed

APPLICATION DOCUMENT CHECKLIST

(To be returned with application form)

1. Covering letter from MMUH/MPH Principal Investigator ☑

2. Application Form ☑
3. Hospital Application Fee
4. Research Study Protocol ☑

   •Background and rationale
   •Objectives & endpoints/outcome measures
   •Study design
   •Treatment of study subjects
   •Safety reporting
   •Statistics
   •Data handling and record keeping
   •Retention of essential documents –minimum 5 years
   •Quality Control & Quality Assurance procedures
   •Audits and inspections
   •Ethics
   •Financing and Insurance/Indemnity
   •Clinical Study Report and publication policy
   •References
5. Summary of Protocol ☑
6. ~~Health Products Regulatory Authority authorization (formerly known as Irish Medicines Board)~~ Non-applicable

7. Consent Form (identify with version number and number each page, on headed paper) ☑

8. Participant Information Leaflet (identify with version number and number each page, on headed paper) ☑

9. ~~Agreements (between Sponsor and other parties)~~ Non-applicable
10. ~~Sponsors Indemnity~~ Non-applicable

11. ~~Insurance Certificate~~ Non-applicable

12. ~~Copy of letter of notification to patient's GP (on headed paper)~~ Non-applicable
13. ~~Any questionnaire which participant may be asked to complete~~ Non-applicable
14. ~~Any advertisement or circular used in recruitment~~ Non-applicable

15. MMUH and/or MPH Principal Investigator's ***and*** Co-Investigator's up-to-date Curriculum Vitae ☑

16. Sixteen ***collated and securely bound*** copies of ***all*** the above documents (including this checklist) ☑

(plastic covers are not adequate as a secure method of binding)

Please send all the above to:

Ms Sarah O'Neill, Administrator, Institutional Review Board, Mater Misericordiae University Hospital, Telephone: 01-8032971 e-mail: soneill@mater.ie

Receipt of completed, valid submissions by the deadline date does not guarantee that submission will be reviewed at next meeting

Appendix 4.3: Ethical Approval

Mater Misericordiae
University Hospital
Sisters of Mercy
Eccles Street, Dublin D07 R2WY, Ireland

Ospidéal Ollscoile
Mater Misericordiae
Siúracha na Trócaire
Sráid Eccles, Baile Átha Cliath D07 R2WY, Éire

Tel: +353 1 8032000 Fax: +353 1 8032404 Web: www.mater.ie

Not for prescription purposes

Mr Sean Paul Teeling
Assistant Professor
Mater Lean Academy Academic Head
Transformation Office
Mater Misericordiae University Hospital
Eccles Street
Dublin 7

24th October 2018

Institutional Review Board Reference: 1/378/2022

RE: The influence of Lean Six Sigma on person-centredness, person-centred care and cultures in a major teaching hospital in Ireland
Research Protocol, 30th August 2018
Information Leaflet for workshop/interview Participant
Participant Consent Form

Dear Mr Teeling

The Mater Misericordiae University Hospital and Mater Private Hospital Institutional Review Board (IRB) at its meeting of Wednesday 24th October 2018 discussed the above research study to be carried out at the Mater Misericordiae University Hospital (MMUH).

Approval to proceed with this research study at the MMUH is granted; this approval is valid until 24th October 2020.

The IRB recommends that the selection of participants for this research study should have an unbiased approach and be carried out by an independent person; the IRB should be advised if the Research Protocol is changed as a result.

It is your responsibility to adhere to the approved study protocol and ensure that all investigators involved with the research only use the approved documents without deviation (unless they have been approved by the IRB), to submit annual reports setting out the progress of the research (giving details of the number of participants who have been recruited, the number who have completed the study and details of any adverse events etc.) and to notify the IRB when the research is concluded.

The MMUH and Mater Private Hospital IRB would like to remind all investigators involved in research of their legal obligations under the law on Data Protection.

Yours sincerely

Prof Malcolm Kell
Chairman
Institutional Review Board

Appendix 4.4: Letter of invitation and participant information leaflet

Information Leaflet for workshop/interview Participant

Title of Study: The contribution of Lean Six Sigma to person-centred cultures in a university hospital

You are being invited to participate in a research study. Thank you for taking time to read this information leaflet.

RESEARCH TEAM: Seán Paul Teeling, joint appointment with the Mater Misericordiae University Hospital (Mater Lean Academy) and UCD Health Systems is the Principal Investigator (PI) on this research project. My contact details are included at the end of this document.

WHAT ARE THE OBJECTIVES OF THIS STUDY? The purpose of the study is to *evaluate the influence that the Lean Six Sigma (Lean Six Sigma) Programme in the Mater Misericordiae University Hospital (MMUH) has on person-centred care and cultures.*

WHY HAVE I BEEN INVITED TO TAKE PART? You have been approached to participate in this research as you are a Graduate of the UCD Mater Lean Academy Professional Certificate in Lean Six Sigma (Green Belt)
Programme. I am interested in exploring with you if and in what ways your involvement in the academy training has influenced person-centred care and cultures within the MMUH.

WHAT WILL HAPPEN IF I VOLUNTEER? Your participation is entirely voluntary. If you agree to participate, you will be invited to take part in a 2 facilitated workshops within a 4 month period (each of 2 hour duration) with other qualified Lean practitioners currently working within the hospital and in an individual interview (40 minutes) on the outcomes of workshop 1 (in relation to your own Lean Six Sigma project outcomes) before workshop 2.

The workshops will use person-centred approaches to work with you regarding your experience of being a Lean Six Sigma Green Belt within MMUH. Photography will

take place of materials and settings but not of you or other participants. You will not be asked about specific patients or staff.
Workshops will be scheduled for Lunch times and lunch will be provided to all participants on all occasions. Dietary requirements will be sought once participants are confirmed.
The individual interviews will be audio recorded, however this data will be transcribed and anonymised and you will have an opportunity to review this transcription prior to it being used in the analysis.

CONFIDENTIALITY: I will be responsible for maintaining the anonymity of the facilitated workshop discussion and interviews. All information collected as part of the study will be stored securely on password protected computers within the Mater Misericordiae University Hospital. All participants will be reminded of the need to respect all other participants' confidential information prior to the workshops and at the end.

WHAT ARE THE BENEFITS OR RISKS ASSOCIATED WITH THE STUDY? While there will be no direct benefit to you from the study, the findings have the potential to make a contribution to our understanding of the effectiveness of Lean Six Sigma programmes on the development of person-centred cultures of care. As such, the findings from this study will be presented at hospital, university level and at national and international conferences. The findings will also be submitted for publication in peer-reviewed journals. However no individual participant will be identified in any publication or presentation and only anonymised quotes will be used in these reports and publications. There are no known risks associated with participation.

RIGHT TO WITHDRAW: You can decide to withdraw from the study at any point prior to the transcripts being anonymised without any consequence. You can contact the researcher to request this.

HOW WILL MY INFORMATION BE USED? Your views will be combined with those of others and used to develop an understanding of - if and in what ways Lean Six Sigma in healthcare contributes to person-centredness, person-centred care and cultures. Once the data have been anonymised it will not be possible to withdraw from the study.

NEXT STEPS: If you are willing to take part in the study I would ask you to please return the attached consent form to me via internal post to the address below, via e-mail or by calling to my office, whichever is most convenient to you.

FURTHER INFORMATION & CONTACT DETAILS: If you have any further questions about the research or would like information on the findings, you can contact:

Seán Paul Teeling
Assistant Professor Health Systems/Mater Lean Academy

UCD School of Nursing, Midwifery and Health Systems
Affiliate member, Centre for Person-centred Practice Research, QMU Edinburgh

Transformation Office, Mater Misericordiae University Hospital, Eccles St., Dublin 7
Tel: +353-1-8097460; Mobile: 0872862969; Email: steeling@mater.ie
Website Mater Lean Academy

Appendix 4.5: Participant Consent Form

PARTICIPANT CONSENT FORM

Title of Study: The contribution of Lean Six Sigma to person-centred cultures in a university hospital

PARTICIPANT CONSENT FORM

By signing and returning this consent form you are indicating your agreement with the following statements:

- I have read and understood the attached *Participant Information Leaflet* for this study.
- I have had the opportunity to ask questions and discuss the study. (Note you can contact Seán Paul Teeling the PI on steeling@mater.ie/7460/0872862969).
- I have received satisfactory answers to all my questions, where I have had a query.
- I have received enough information about this study.
- I understand that the facilitated workshop will involve photography, but this is of the materials and outputs and not of me personally
- I understand interviews will be recorded, transcribed and anonymised
- I understand I am free to withdraw from the study at any time until the transcripts are anonymised and have become part of the study data.
- I understand anonymised data will be used as part of PhD research
- I agree to take part in the study.

Participant's Signature: _____
Date:
Participant's Name in Print: _____

Contact Email: _____

Appendix 4.6: Interview Framework

Introduction

Hi (name). Thanks again for coming today and for your continued participation in this research I sincerely appreciate it. Just to confirm, as per the consent form that you kindly signed that you're happy to continue to participate in this interview and in the final workshop.

If you can cast your mind back to the first workshop that you attended - a few people who have engaged with the UCD programme talked about their experience of it and how they thought the intervention and their engagement with it did or did not impact on their workplace culture. I have the outcomes from all three of the first workshops with me today for us to consider, which I have summarised in this colour coded sheet and pictures of the objects which people brought with them for the workshops. For ease of reference the colour codes match those we used for the storyboards in the workshop for the specific CMOs.

I wonder if today we could look at the CMOs that try and describe how Lean works in your workplace or practice area, and take the time to consider some of the issues in more detail. I will be asking you about these ideas and I would like you to help me to get a better understanding about how the Lean Six Sigma programme works/doesn't work to contribute to person-centredness/culture and, person-centred care. So I have a few things I am curious about from looking at the data that I'd like us to explore and unpick together. To facilitate this I have some follow up questions to ask and hopefully we can together unpick what is happening and why in your practice area so the way in which the intervention works on the ground can be better understood.

Context – what conditions are required for a Lean measure to trigger mechanisms?

1. Looking at the feedback from the workshop, most people felt that a contextual factor that can impede Lean improvement is a culture of 'we've always done it

this way'. Could you describe any experience you have had of this in your practice area?

2. The words metrics and Key Performance Indicators (or KPIs) were identified by and discussed by participants. What do you feel about them in relation to your own practice and practice setting? What role do metrics play in your work setting? What do you think of them? Were they (and if so) how were they influential in how Lean was engaged with in your area?
3. Nearly half of people felt that improvement takes place in silos. What has been your experience of this? Do you have any thoughts about why this is occurring in some places and not in others?
4. Expectations on staff who involve in Lean Six Sigma work was not identified in the literature review, but as you will see from the colour chart this was identified within the workshop by a large number of people. What are your thoughts on this?
5. Other themes identified through the workshops were communication, hard work and resources. Do any of these themes have any resonance for you in relation to Lean Six Sigma in your practice and practice area?

Mechanism – what is it about an intervention that may lead to it having a particular outcome? How does the intervention work?

1. The role of management was discussed in our workshops – what has been the role of management in your practice area been in relation to Lean Six Sigma? How has this influenced progress of lean?
2. In relation to the UCD programme and participation with it, several key mechanisms were identified within the Mater Hospital to enable access to it. These included study time and funding, access for all staff grades and disciplines and staff participating because they want to, not because they are sent. Maybe, thinking of these individually, how did you/have you experienced any of these mechanisms in your own time on the programme? Was there anything else that influenced your participation in the programme? If so can you describe that?

3. Can you tell me about your experience of any support you may have had from other staff who have completed Lean training within your practice area and perhaps more widely in the hospital?
4. Who has your Lean Six Sigma programme focused on?
   Staff or patients? Both? Neither? What was behind the decisions you or your colleagues made as to where to focus your improvement work?
5. A number of additional mechanisms to enable Outcomes from the Lean Six Sigma education and training programme intervention were identified in the workshop. These included having access to learning resources, a Lean Academy on-site, protected time to participate in Lean work and support from your own work colleagues? Do any or all of these have resonance with you? Can we discuss?

Outcome/outcome patterns – what are the practical effects in a given context?

There were positive outcomes identified in both the literature and our workshops as a result of implementing Lean Six Sigma. For you , in your place what outcomes have you noticed or are aware of? We might discuss these in relation to what you feel outcomes may or may not be and we can look at the colour chart also to see if any of the workshops have outcomes that may resonate with you.

Prompts:

1. You personally as an individual?
2. You personally within your practice area?
3. Other staff?
4. Patients?
5. Practice routines
6. Team culture
7. The organisation?

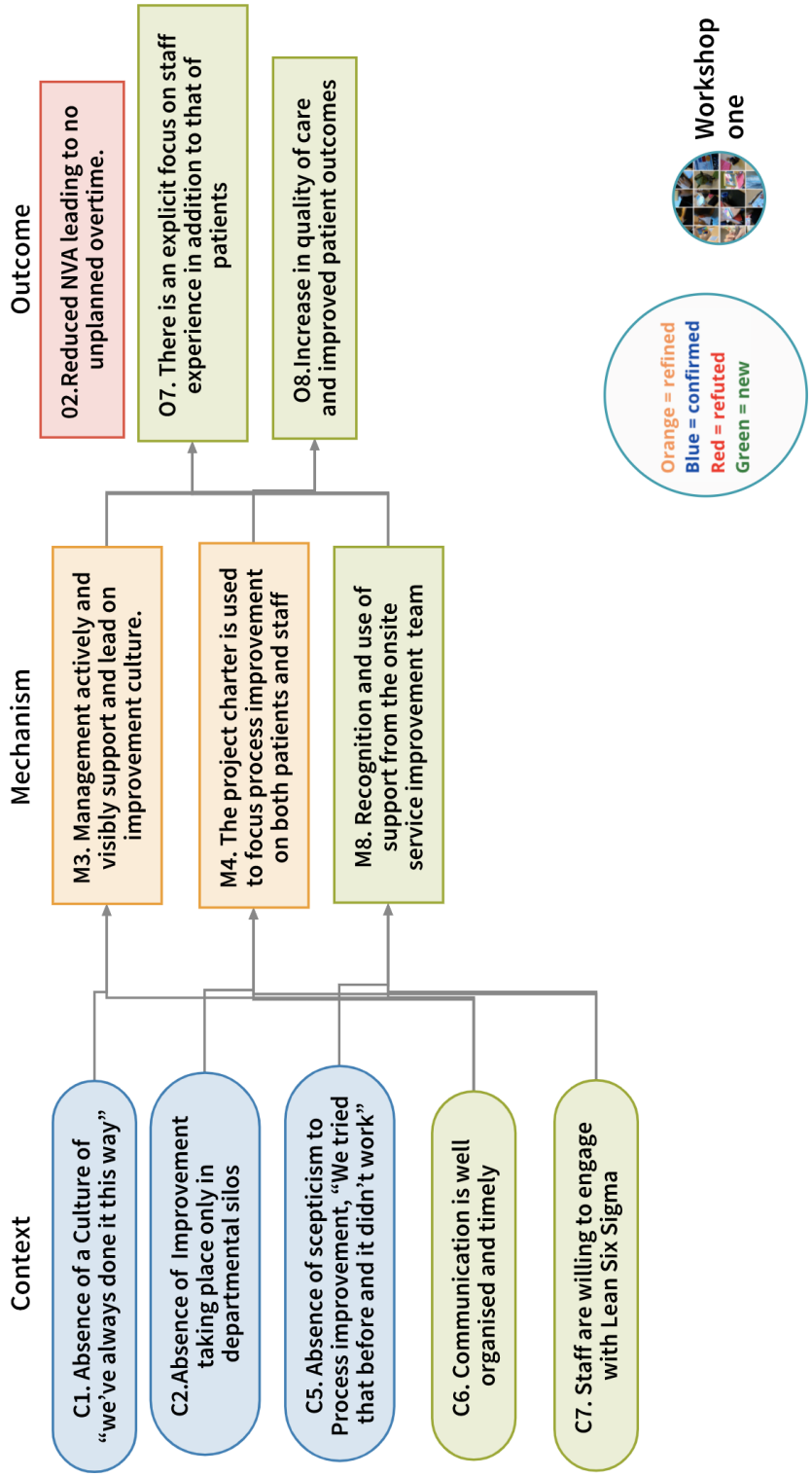
Appendix 4.7: Process Evaluation Listening Skills

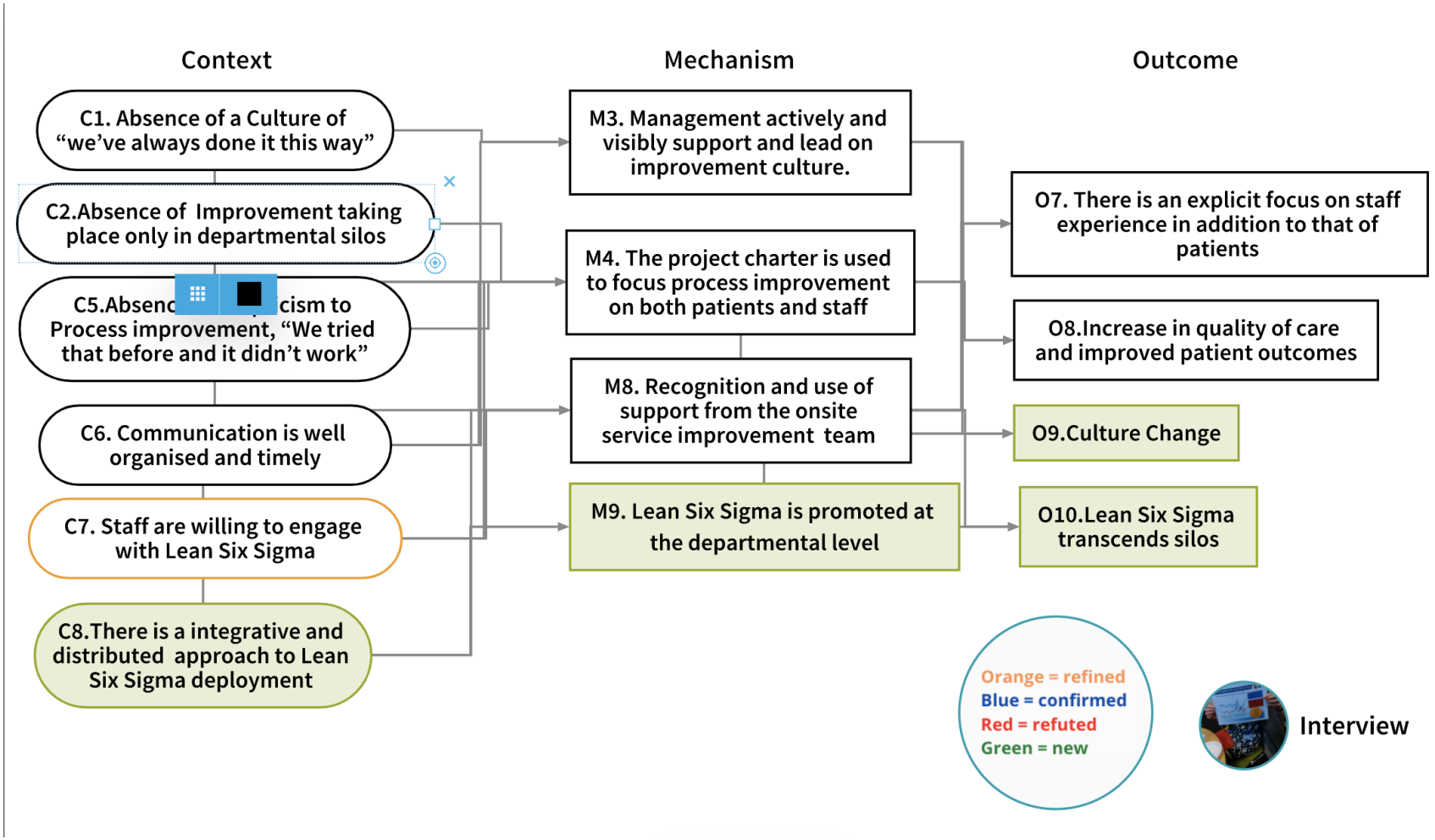
Process evaluation record: Listening Skills

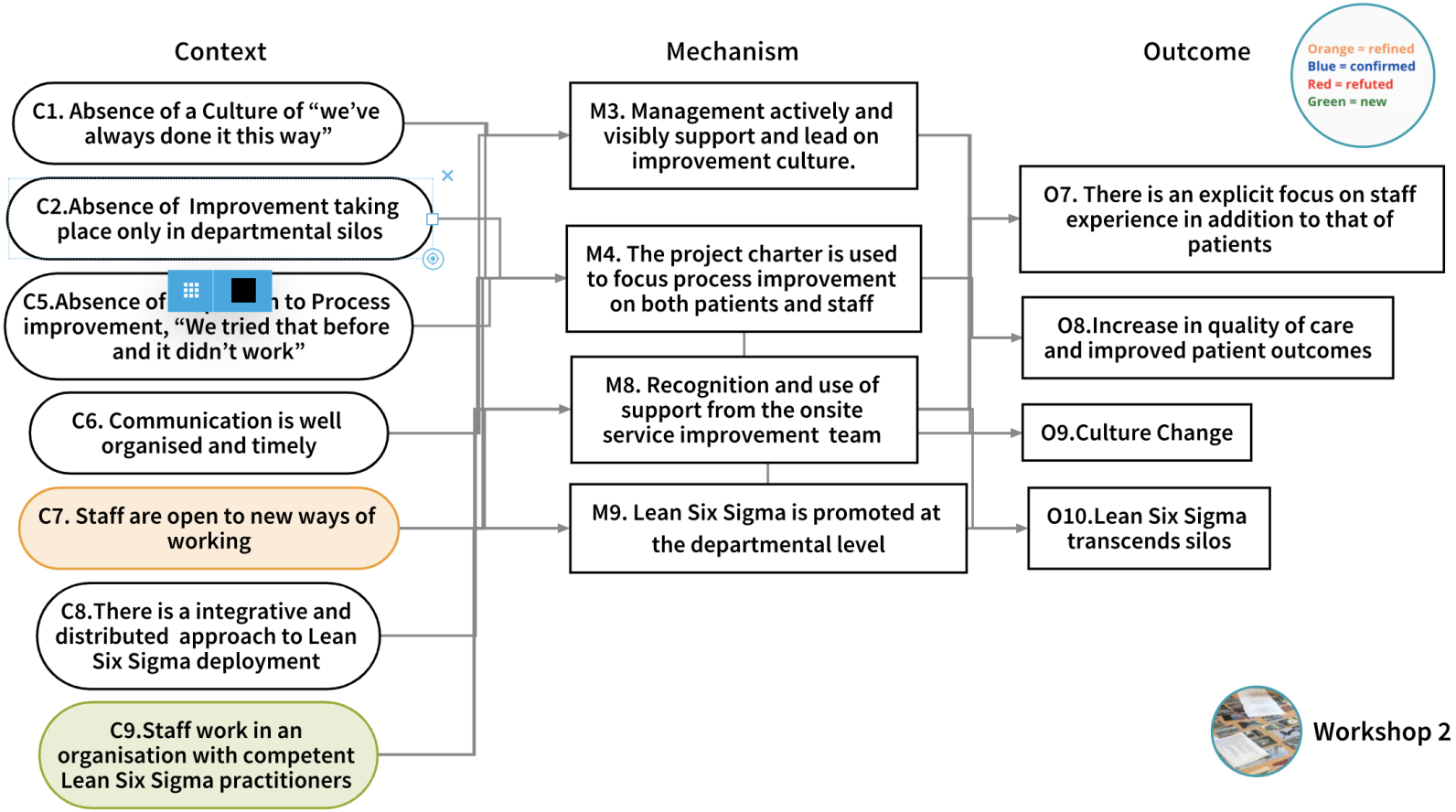
Key question for reflection: **How easy/difficult did I find what my buddy/active learning group members were presenting themselves and saying?**
How easy/difficult did I find it to attend to what was said?
How easy/difficult did I find it to actively listen?
How easy/difficult did I find it to attend to the person's non-verbal behaviour as they were talking?
How easy/difficult did I find it to keep a helpful distance from the person who was sharing?
How easy/difficult di I find interrupting the other person's thoughts and feelings?
How easy/difficult did I find it to break a silence around what they were saying?
How easy/difficult did I find it to stay present throughout?
How easy/difficult did I find it to listen to central content?
How easy/difficult was it for me to make value judgements and/or assumptions?

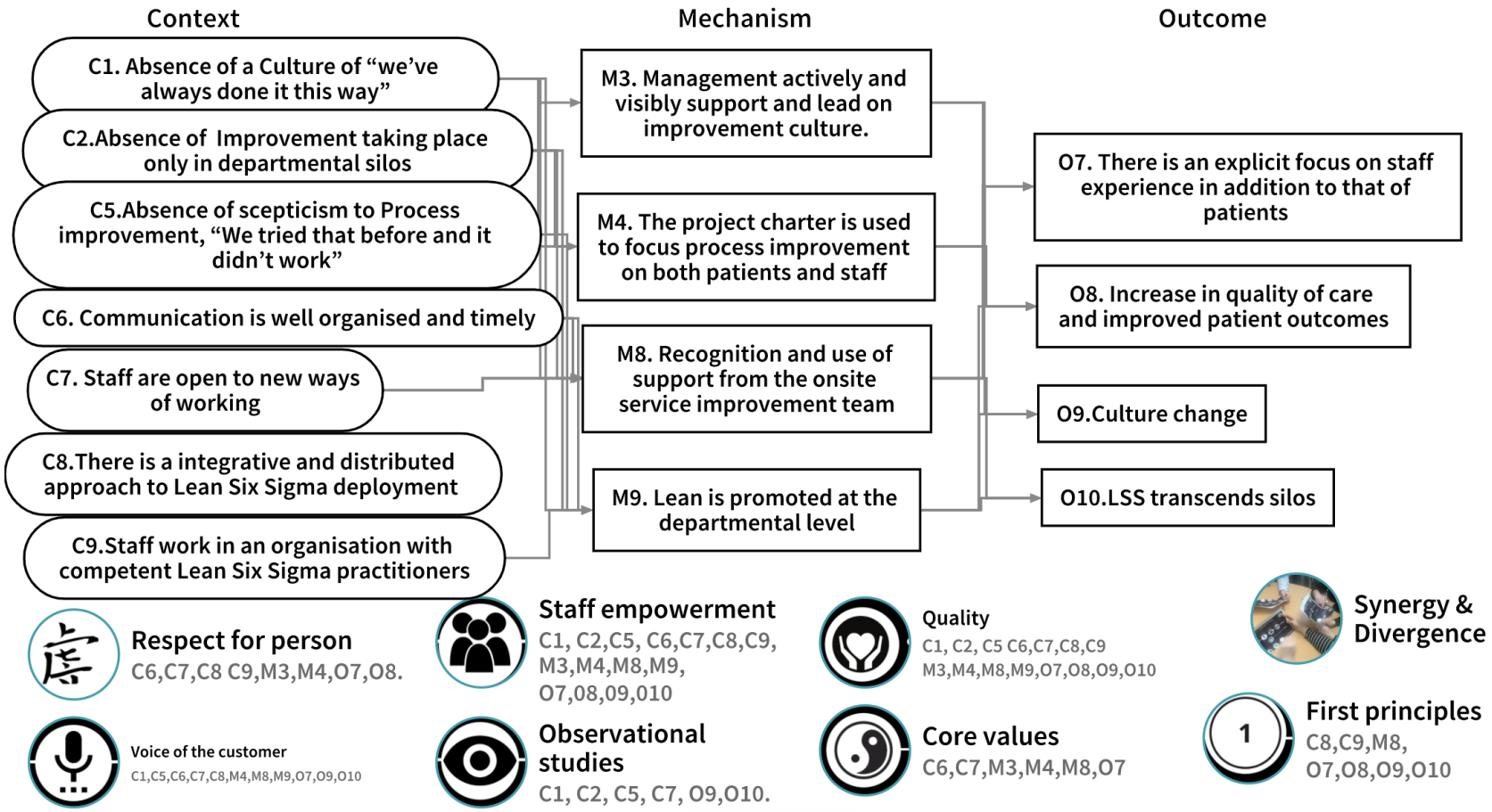
Source: Adapted from Dewing et al. (2014, p 189)

Appendix 5.1: Development of CMOc1 'Aspects of organisational culture'.

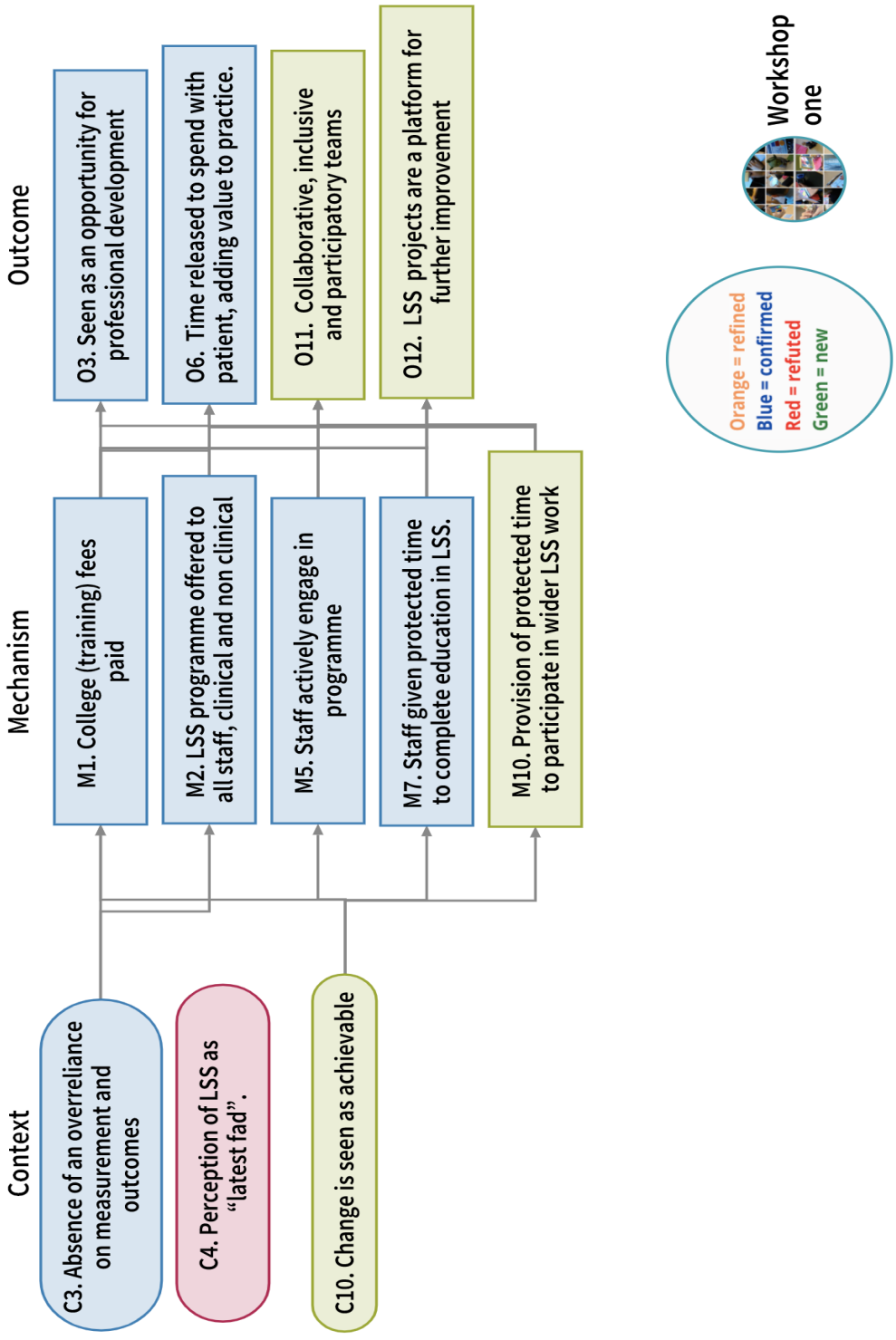


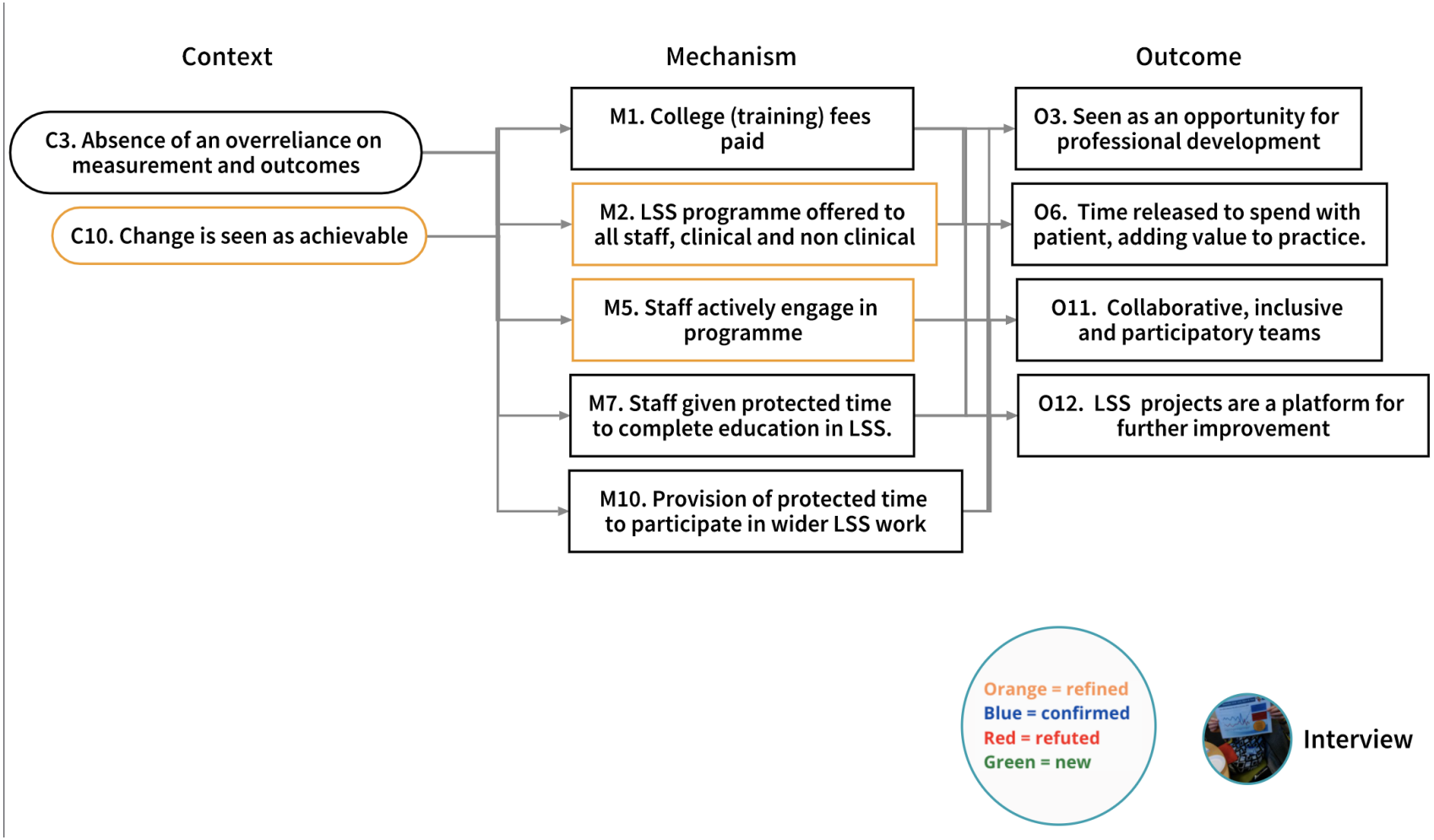

Context
Mechanism
Outcome
C1. Absence of a Culture of "we've always done it this way"
C2.Absence of Improvement taking place only in departmental silos
C5.Absenc cism to Process improvement, "We tried that before and it didn't work"
C6. Communication is well organised and timely
C7. Staff are willing to engage with Lean Six Sigma
C8.There is a integrative and distributed approach to Lean Six Sigma deployment
M3. Management actively and visibly support and lead on improvement culture.
M4. The project charter is used to focus process improvement on both patients and staff
M8. Recognition and use of support from the onsite service improvement team
M9. Lean Six Sigma is promoted at the departmental level
O7. There is an explicit focus on staff experience in addition to that of patients
O8.Increase in quality of care and improved patient outcomes
O9.Culture Change
O10.Lean Six Sigma transcends silos
Orange = refined
Blue = confirmed
Red = refuted
Green = new
Interview

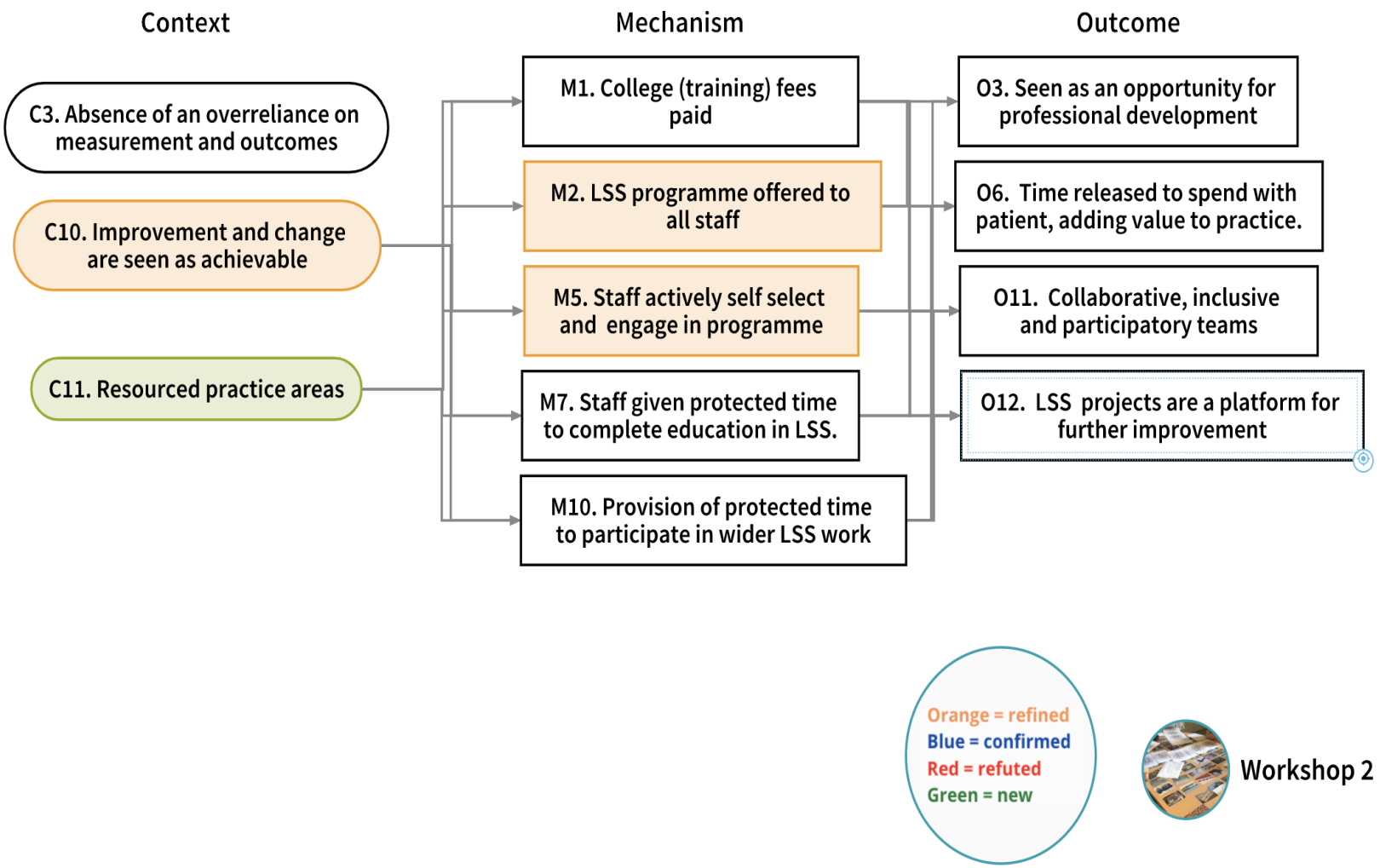

Context
Mechanism
Outcome
Orange = refined
Blue = confirmed
Red = refuted
Green = new
C1. Absence of a Culture of "we've always done it this way"
C2.Absence of Improvement taking place only in departmental silos
C5.Absence of to Process improvement, "We tried that before and it didn't work"
C6. Communication is well organised and timely
C7. Staff are open to new ways of working
C8.There is a integrative and distributed approach to Lean Six Sigma deployment
C9.Staff work in an organisation with competent Lean Six Sigma practitioners
M3. Management actively and visibly support and lead on improvement culture.
M4. The project charter is used to focus process improvement on both patients and staff
M8. Recognition and use of support from the onsite service improvement team
M9. Lean Six Sigma is promoted at the departmental level
O7. There is an explicit focus on staff experience in addition to that of patients
O8.Increase in quality of care and improved patient outcomes
O9.Culture Change
O10.Lean Six Sigma transcends silos
Workshop 2

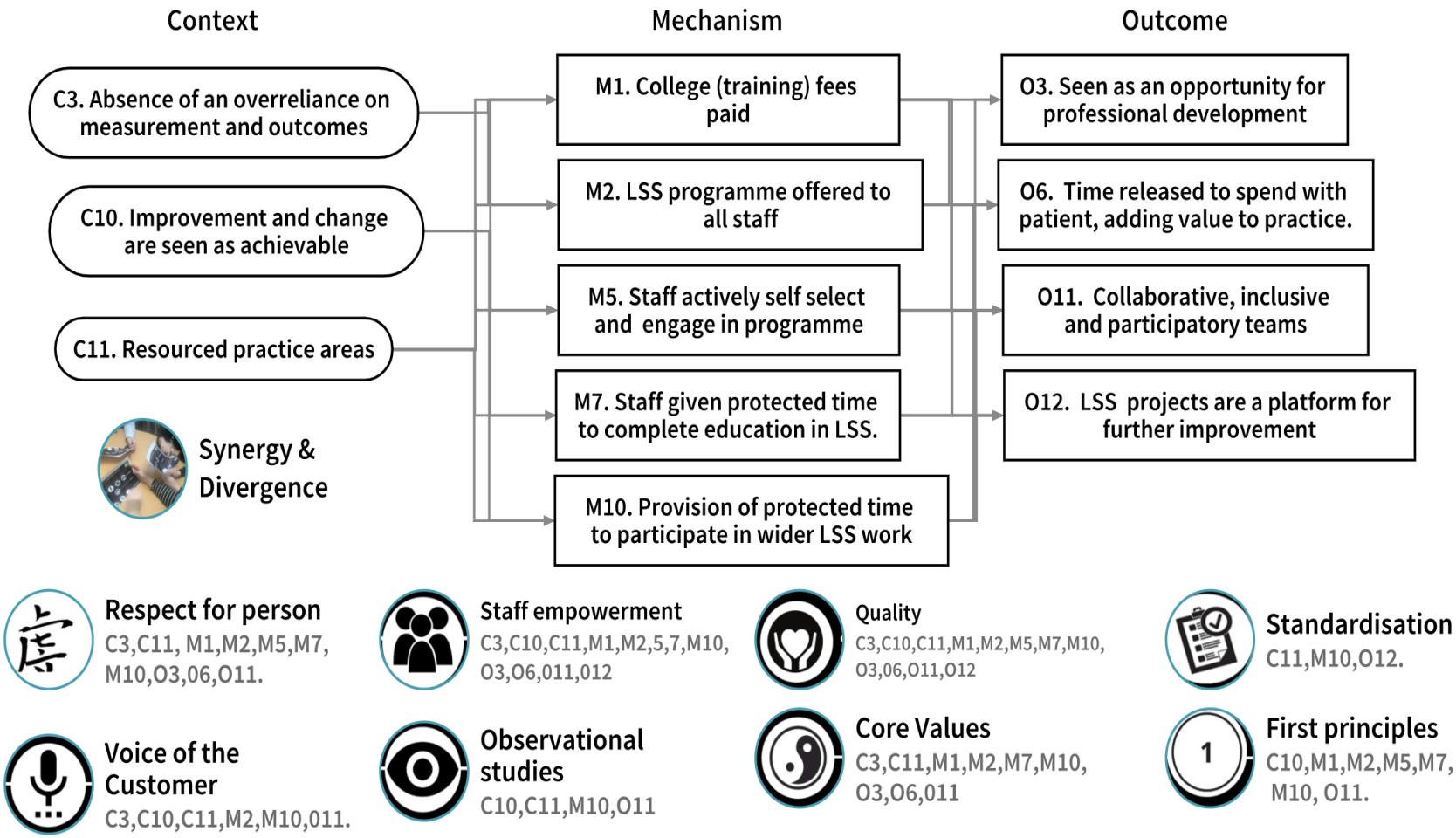

Context
Mechanism
Outcome
C1. Absence of a Culture of "we've always done it this way"
C2.Absence of Improvement taking place only in departmental silos
C5.Absence of scepticism to Process improvement, "We tried that before and it didn't work"
C6. Communication is well organised and timely
C7. Staff are open to new ways of working
C8.There is a integrative and distributed approach to Lean Six Sigma deployment
C9.Staff work in an organisation with competent Lean Six Sigma practitioners
M3. Management actively and visibly support and lead on improvement culture.
M4. The project charter is used to focus process improvement on both patients and staff
M8. Recognition and use of support from the onsite service improvement team
M9. Lean is promoted at the departmental level
O7. There is an explicit focus on staff experience in addition to that of patients
O8. Increase in quality of care and improved patient outcomes
O9.Culture change
O10.LSS transcends silos
Respect for person
C6,C7,C8 C9,M3,M4,O7,O8.
Voice of the customer
C1,C5,C6,C7,C8,M4,M8,M9,O7,O9,O10
Staff empowerment
C1, C2,C5, C6,C7,C8,C9, M3,M4,M8,M9, O7,08,09,010
Observational studies
C1, C2, C5, C7, O9,O10.
Quality
C1, C2, C5 C6,C7,C8,C9 M3,M4,M8,M9,O7,O8,O9,O10
Core values
C6,C7,M3,M4,M8,O7
Synergy & Divergence
1
First principles
C8,C9,M8, O7,O8,O9,O10

Appendix 6.1: Development of CMOc2
'The organisation's receptivity to LSS'

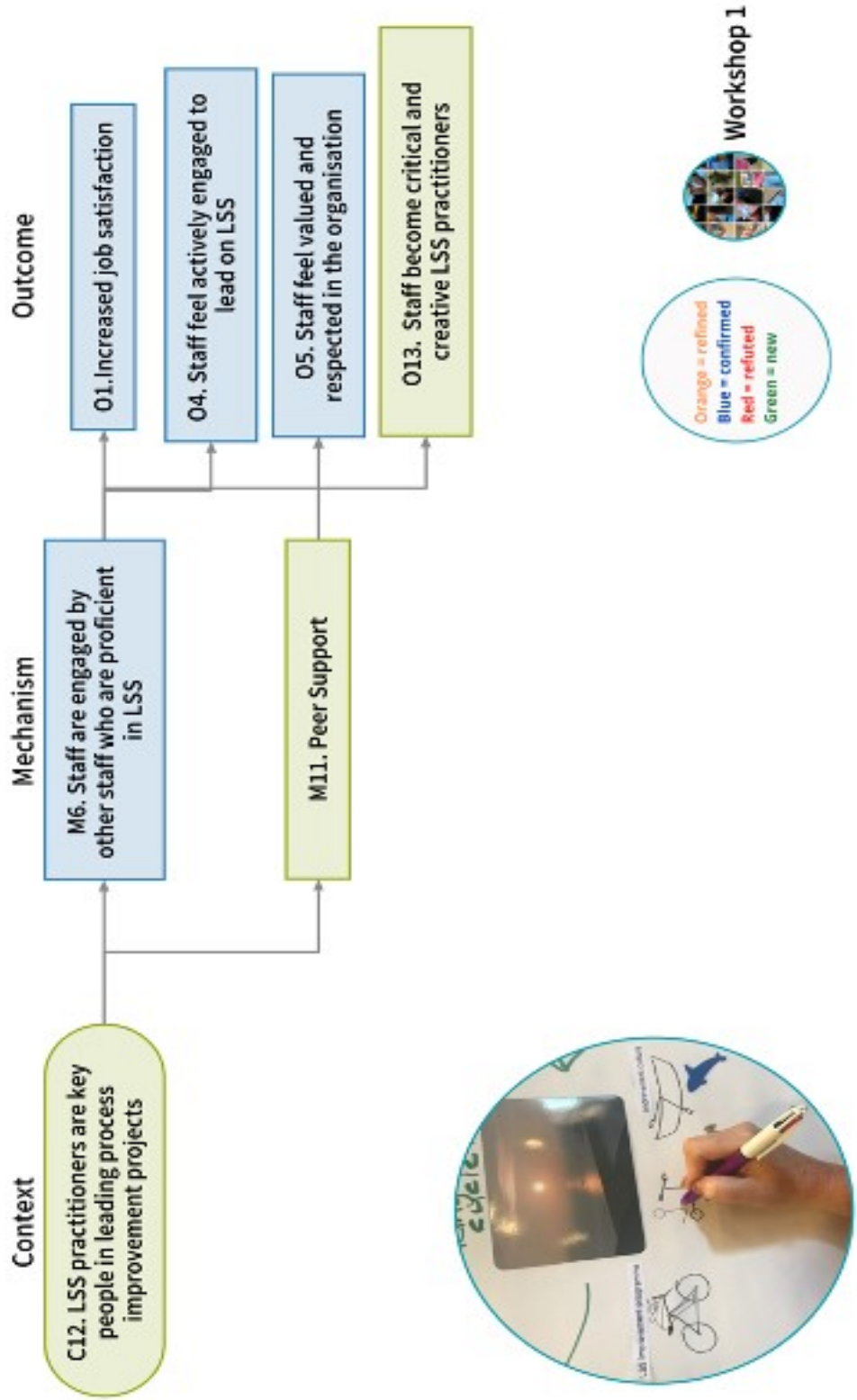


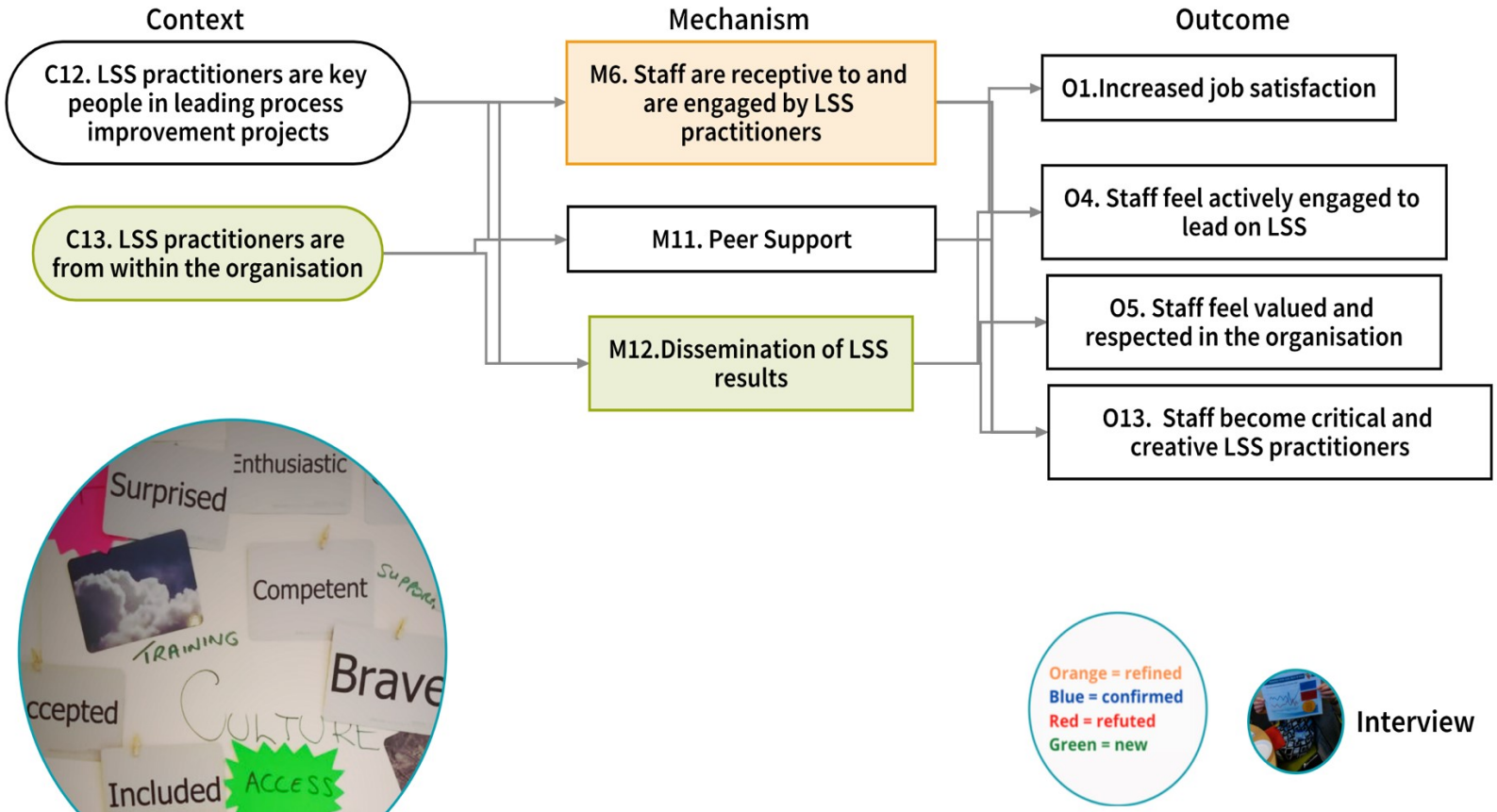

Context
Mechanism
Outcome
C3. Absence of an overreliance on measurement and outcomes
C10. Change is seen as achievable
M1. College (training) fees paid
M2. LSS programme offered to all staff, clinical and non clinical
M5. Staff actively engage in programme
M7. Staff given protected time to complete education in LSS.
M10. Provision of protected time to participate in wider LSS work
O3. Seen as an opportunity for professional development
O6. Time released to spend with patient, adding value to practice.
O11. Collaborative, inclusive and participatory teams
O12. LSS projects are a platform for further improvement
Orange = refined
Blue = confirmed
Red = refuted
Green = new
Interview

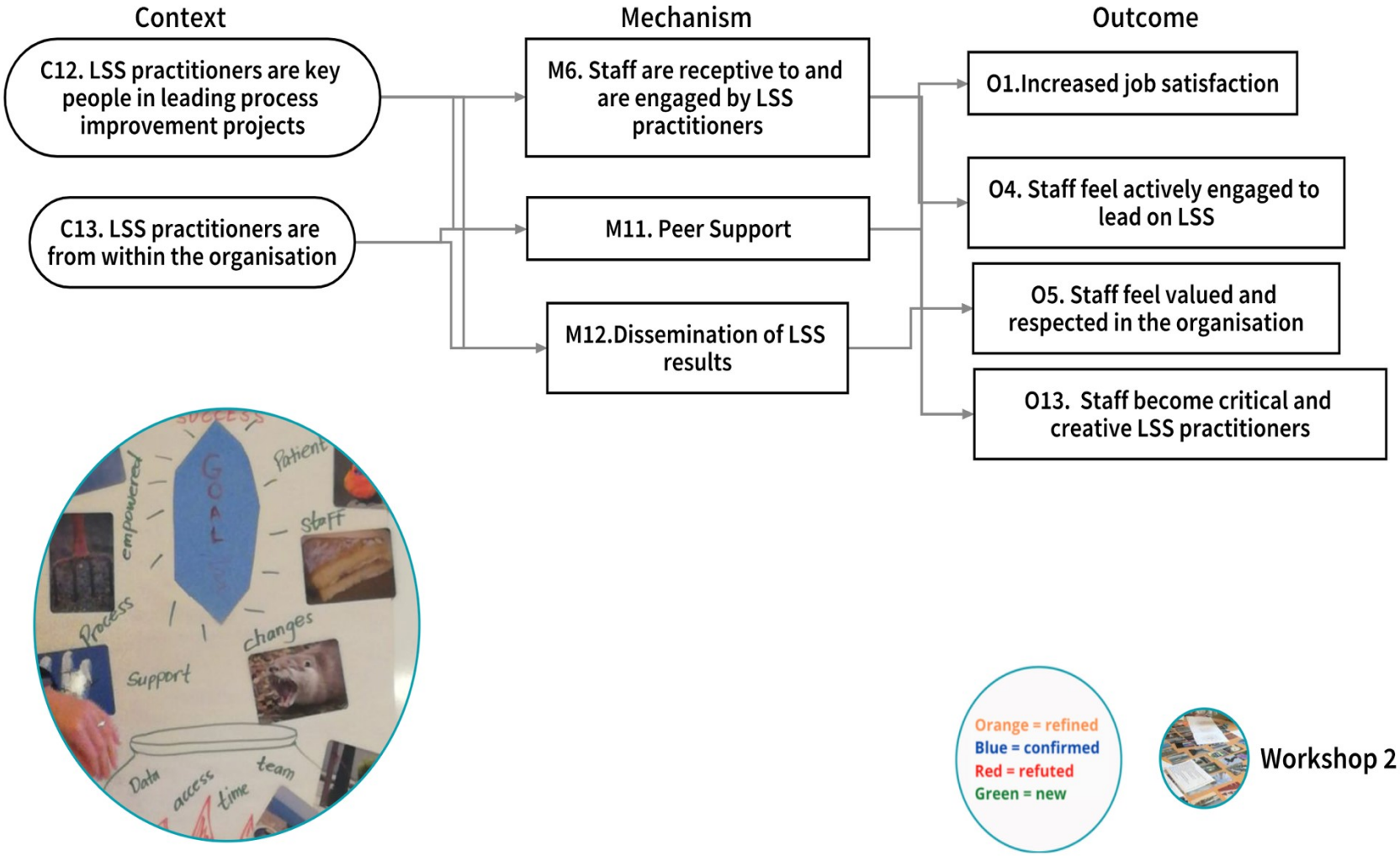

Context
Mechanism
Outcome
C3. Absence of an overreliance on measurement and outcomes
C10. Improvement and change are seen as achievable
C11. Resourced practice areas
M1. College (training) fees paid
M2. LSS programme offered to all staff
M5. Staff actively self select and engage in programme
M7. Staff given protected time to complete education in LSS.
M10. Provision of protected time to participate in wider LSS work
O3. Seen as an opportunity for professional development
O6. Time released to spend with patient, adding value to practice.
O11. Collaborative, inclusive and participatory teams
O12. LSS projects are a platform for further improvement
Orange = refined
Blue = confirmed
Red = refuted
Green = new
Workshop 2

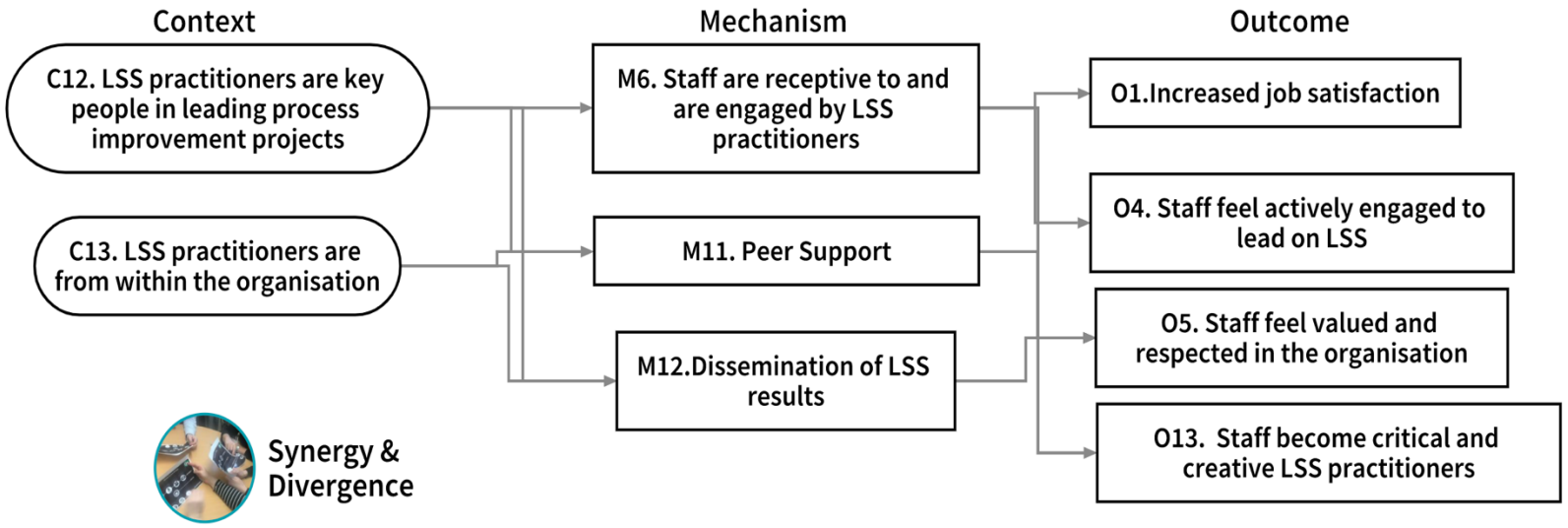

Context
Mechanism
Outcome
C3. Absence of an overreliance on measurement and outcomes
C10. Improvement and change are seen as achievable
C11. Resourced practice areas
Synergy & Divergence
M1. College (training) fees paid
M2. LSS programme offered to all staff
M5. Staff actively self select and engage in programme
M7. Staff given protected time to complete education in LSS.
M10. Provision of protected time to participate in wider LSS work
O3. Seen as an opportunity for professional development
O6. Time released to spend with patient, adding value to practice.
O11. Collaborative, inclusive and participatory teams
O12. LSS projects are a platform for further improvement
Respect for person
C3,C11, M1,M2,M5,M7, M10,O3,06,O11.
Staff empowerment
C3,C10,C11,M1,M2,5,7,M10, O3,O6,011,012
Quality
C3,C10,C11,M1,M2,M5,M7,M10, O3,06,O11,O12
Standardisation
C11,M10,O12.
Voice of the Customer
C3,C10,C11,M2,M10,011.
Observational studies
C10,C11,M10,O11
Core Values
C3,C11,M1,M2,M7,M10, O3,O6,011
First principles
C10,M1,M2,M5,M7, M10, O11.

Appendix 7.1: Development of CMOc3 'Participants' self-perception as LSS practitioners'




Context
Mechanism
Outcome
C12. LSS practitioners are key people in leading process improvement projects
C13. LSS practitioners are from within the organisation
M6. Staff are receptive to and are engaged by LSS practitioners
M11. Peer Support
M12.Dissemination of LSS results
O1.Increased job satisfaction
O4. Staff feel actively engaged to lead on LSS
O5. Staff feel valued and respected in the organisation
O13. Staff become critical and creative LSS practitioners
Surprised
Enthusiastic
Competent
TRAINING
Brave
CULTURE
Included
ACCESS
Orange = refined
Blue = confirmed
Red = refuted
Green = new
Interview


Context
Mechanism
Outcome
C12. LSS practitioners are key people in leading process improvement projects
C13. LSS practitioners are from within the organisation
M6. Staff are receptive to and are engaged by LSS practitioners
M11. Peer Support
M12.Dissemination of LSS results
O1.Increased job satisfaction
O4. Staff feel actively engaged to lead on LSS
O5. Staff feel valued and respected in the organisation
O13. Staff become critical and creative LSS practitioners
SUCCESS
GOAL
Patient
empowered
staff
Process
changes
Support
Data
access
time
team
Orange = refined
Blue = confirmed
Red = refuted
Green = new
Workshop 2



Respect for person
C12,C13,M11,O5.

Staff empowerment
C12,C13,M1,O1,O4,O5, O13

Quality
C12,C13,M11,O1,O4,O5,O 13

Standardisation
C12,C13,M6,O4,O5, O13

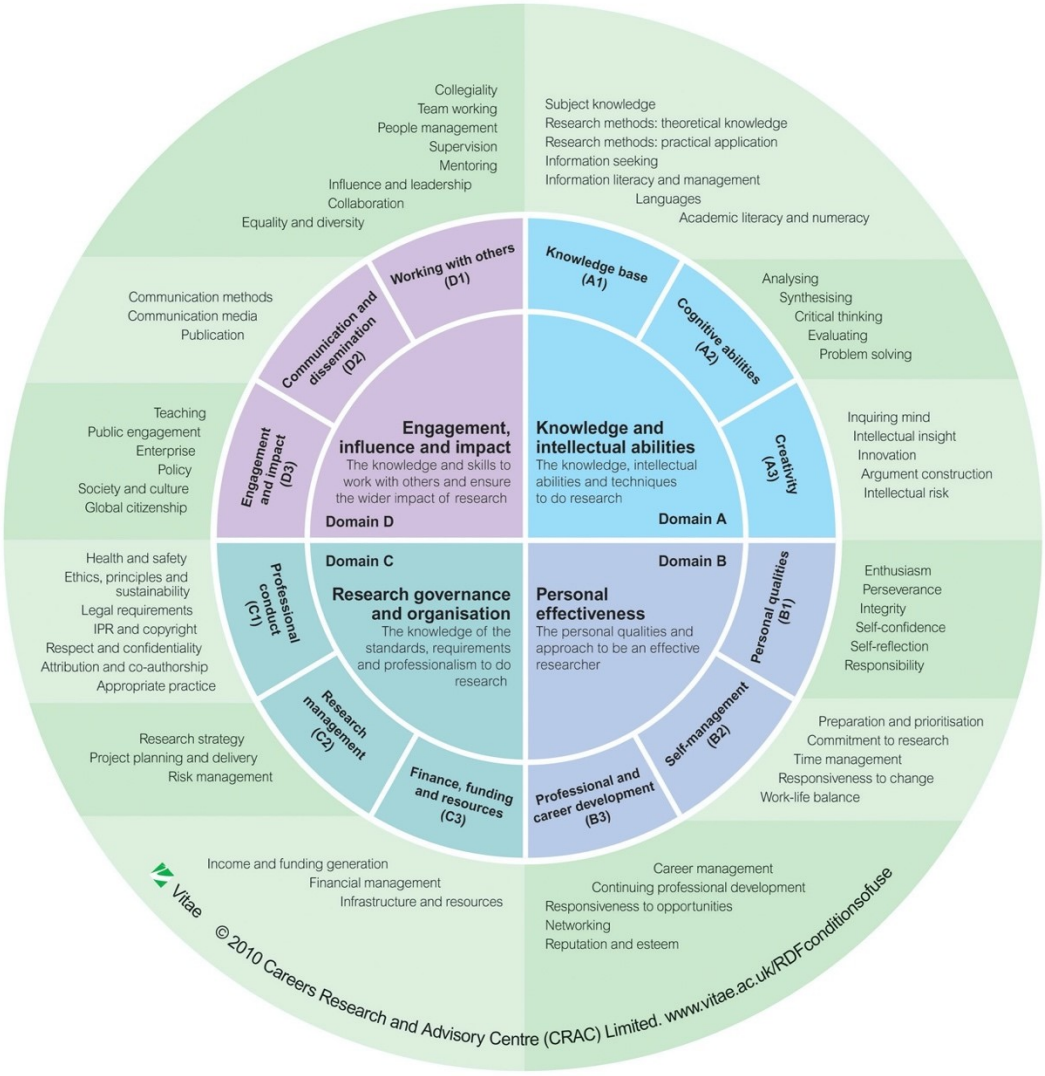
Voice of the Customer
C12,C13,M6,O5

Observational studies
C12,C13,M6,O4,O5

Core Values
C142C13,M11,O5.

First principles
C12,C13,M6,M11,O1, O4,O5.

Appendix 8.1 Researcher Development framework



Source: Vitae Researcher Development Framework, taken from the Vitae Website (2011)